TITLE 856 INDIANA BOARD OF PHARMACY

ARTICLE 1. PHARMACIES AND PHARMACISTS

Rule 1. Application Requirements (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 1.1. Definitions

856 IAC 1-1.1-1 Adoption of definitions

Authority: IC 25-26-13-4
Affected: IC 25-26-13-2; IC 35-48-1-1

Sec. 1. All terms which are defined in IC 25-26-13-2 shall have the same meanings as they are so defined when used in the rules and regulations of the Indiana board of pharmacy found in Article 1 of Title 856 of the Indiana Administrative Code. *(Indiana Board of Pharmacy; 856 IAC 1-1.1-1; filed Dec 3, 1985, 3:02 pm: 9 IR 767; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; errata filed Jan 9, 2002, 4:20 p.m.: 25 IR 1645)*

856 IAC 1-1.1-2 "Pharmacy Practice Act" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 2. The term "Pharmacy Practice Act" when used in these regulations is in reference to Acts 1977, Public Law codified at IC 25-26-13 as amended from time to time. *(Indiana Board of Pharmacy; 856 IAC 1-1.1-2; filed Dec 3, 1985, 3:02 pm: 9 IR 767; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; errata filed Jan 9, 2002, 4:20 p.m.: 25 IR 1645)*

856 IAC 1-1.1-3 "In personal attendance" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 3. The term "in personal attendance" as the same is in IC 25-26-13-18(a) of the Pharmacy Practice Act means being physically present in the area specified as the dimensions of the pharmacy in the relevant pharmacy permit application. *(Indiana Board of Pharmacy; 856 IAC 1-1.1-3; filed Dec 3, 1985, 3:02 pm: 9 IR 767; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; errata filed Jan 9, 2002, 4:20 p.m.: 25 IR 1645)*

Rule 2. Pharmacists' Certificate

856 IAC 1-2-1 Display of certificate

Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 1. Certificates of licensure shall be conspicuously displayed in the drugstore, pharmacy, hospital, dispensary or other place where drugs are sold or dispensed and where the owner or holder thereof is in employment. Failure to comply with this rule shall be deemed sufficient cause for suspension or revocation of the license. *(Indiana Board of Pharmacy; Reg 2,Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)*

856 IAC 1-2-2 Illegal display of certificate; prohibition

Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 2. The display of a certificate of licensure as a pharmacist in a drugstore, pharmacy, hospital, dispensary, or other place where drugs are sold or dispensed, and in which place the owner and holder of such license is not in bona fide employment, shall

be deemed an illegal use of such license, and upon satisfactory proof of such illegal use, such license may be revoked. *(Indiana Board of Pharmacy; Reg 2,Sec 2; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)*

856 IAC 1-2-3 Notification of address change

Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 3. All holders of a license as a pharmacist shall notify the Indiana board of pharmacy of any change of address. *(Indiana Board of Pharmacy; Reg 2,Sec 3; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)*

856 IAC 1-2-4 Service by mail sufficient notice

Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 4. The Board has no way of knowing whether or not a notice reaches its destination and, therefore, when a notice has been mailed to the person concerned, the duty of the Board has been performed. *(Indiana Board of Pharmacy; Reg 2,Sec 4; filed Jun 18, 1962, 10:00 am: Rules and Regs. 1963, p. 119; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-2-5 Duplicate certificate or drugstore permit; fees (Repealed)

Sec. 5. *(Repealed by Indiana Board of Pharmacy; filed Aug 12, 1987, 9:45 am: 11 IR 94)*

Rule 3. Experience (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 3.1. Examination and Experience Requirements

856 IAC 1-3.1-1 Licensure by examination

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. All pharmacist applicants for licensure by examination qualified by law and as provided in rules of the board shall take the complete examination consisting of North American Pharmacist Licensure Examination (NAPLEX™) and the Multistate Pharmacy Jurisprudence Examination (MPJE™). All exams shall be given in the English language only. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-1; filed Dec 3, 1985, 3:02 p.m.: 9 IR 767; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2876; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-3.1-2 Information for licensure

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 2. (a) Persons seeking licensure by examination shall file an application on a form supplied by the board.

(b) Persons seeking licensure by examination shall provide the following information on, or submit such information with, the application for licensure:

(1) Complete name, address, and telephone number.
(2) Date and place of birth.
(3) Certification of complete history and structure of hours of pharmacy experience prior to and after graduation.
(4) Intern/extern certificate number, including date and state from which certificate was issued.

(5) Two (2) recent passport-type (2″× 2″) photographs of the applicant, taken within eight (8) weeks prior to filing the application.
(6) The fee as required by 856 IAC 1-27-1.
(7) Either:
(A) certification of graduation from a program approved by the board pursuant to 856 IAC 1-5-1; or
(B) in the case of an applicant applying in the last half-year of the curriculum, certification from the dean of an approved pharmacy program that the applicant is expected to successfully complete the curriculum;
however, the applicant shall not be allowed to sit for the examination until the board has received certification of graduation. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-2; filed Dec 3, 1985, 3:02 p.m.: 9 IR 767; filed Aug 12, 1987, 9:45 a.m.: 11 IR 94; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2876; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-3.1-3 Passing scores
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 3. To successfully pass an examination, the applicant must attain a general average of not less than seventy-five (75) on the examination taken after the effective date of this rule. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-3; filed Dec 3, 1985, 3:02 p.m.: 9 IR 767; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)*

856 IAC 1-3.1-4 Reexamination
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 4. If an applicant fails an examination or any portion of an examination and wishes to retake the failed portions, the applicant shall file a new complete application, except that the applicant may include affidavits or data concerning his or her experience in a pharmacy and attendance at a college or school of pharmacy by referring to the original application. An applicant who fails to pass a portion of the examination after two (2) sittings shall be permitted to take subsequent examinations, providing the candidate first both appears before the board for consultation, and receives the express written permission of the board. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-4; filed Dec 3, 1985, 3:02 p.m.: 9 IR 767; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)*

856 IAC 1-3.1-5 Pharmacist intern/extern; experience requirement
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 5. The period of practical experience required by law for an applicant for a pharmacist license shall be computed and credited from the date of registration as a pharmacist intern/extern, with no credit given for any experience in pharmacy prior to registration or during a period when the registration has lapsed or is suspended or revoked by the board. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-5; filed Dec 3, 1985, 3:02 p.m.: 9 IR 768; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2876; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-3.1-6 Board approval required for practical experience programs for pharmacist intern/extern registration; pharmacy permit required, exceptions; prior approval of nonpharmacy experience site; minimum-maximum hours of practical experience
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 6. (a) The Indiana board of pharmacy (board) shall approve all practical experience programs wherever served. Persons responsible for the integrity and content of practical experience programs shall furnish information regarding material changes to the board, prior to implementation, for approval of the program. Approval may be withheld for cause, which may include, but is not limited to, unapproved material change in the program or change in program administration.

(b) All persons wishing to satisfy their practical experience requirements in Indiana shall possess a valid registration as a pharmacist intern or extern in Indiana while the practical experience hours are being served.

(c) If the experience is in a pharmacy that is required by law to have a pharmacy permit, that pharmacy must have a valid pharmacy permit. A pharmacy permit is not required if:

(1) the practical experience is being obtained at a site other than a pharmacy, for example, sites primarily engaged in:

(A) manufacturing;

(B) research;

(C) consulting;

(D) drug information;

(E) drug utilization review; or

(F) other pharmacy-related activity; or

(2) the experience is in a pharmacy that is not required to have a permit, for example, federally owned facilities.

(d) Prior approval is required for experience in a site other than a pharmacy. A written request must be submitted to the board prior to beginning the experience period if:

(1) an individual intern or preceptor is seeking board approval, the request for approval shall include:

(A) a detailed description of the proposed practical experience program with respect to time, place, duties, responsibilities, and supervision; and

(B) the name of the person responsible for supervising the experience; or

(2) an approved college or school of pharmacy is seeking board approval for experiential courses, the request for approval shall include:

(A) a detailed description of the proposed practical experience course with respect to duties, responsibilities, and supervision; and

(B) the name of the course coordinator responsible for site selection and maintenance of the integrity of the program.

(e) Acceptable practical experience time per week shall consist of not less than four (4) and not more than sixty (60) hours of time per week served under the supervision of a pharmacist or another board approved practical experience supervisor. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-6; filed Dec 3, 1985, 3:02 p.m.: 9 IR 768; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2876; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)*

856 IAC 1-3.1-7 Pharmacist intern/extern; program requirements

Authority: IC 25-26-13-4
Affected: IC 25-26-13-2

Sec. 7. (a) Practical experience requirements for pharmacist interns/externs in Indiana may be satisfied by complying with either of the following:

(1) Completion of the practical experience requirements of the college or school of pharmacy from which the intern/extern has graduated, if the curriculum of the college or school has been accredited by:

(A) the American Council on Pharmaceutical Education (ACPE);

(B) the Canadian Council on Pharmacy Accreditation (CCPA); or

(C) another board-approved practical experience program.

(2) In the event the intern/extern has graduated from a nonaccredited program as outlined in subdivision (1) or has no practical experience as a part of that individual's educational curriculum, the intern/extern must complete a minimum of one thousand five hundred (1,500) hours of practical experience under the supervision of a pharmacist and provide the board, prior to or concurrent with application for licensure, a written description of the objectives and duties of that experience.

(b) If a candidate for licensure as a pharmacist in Indiana has been licensed as a pharmacist in another state or jurisdiction and has been engaged in the practice of pharmacy as defined in IC 25-26-13-2 for a period of not less than one (1) year, the practical experience requirement is waived. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-7; filed Dec 3, 1985, 3:02 p.m.: 9 IR 768; filed Jan 3, 2000, 10:03 a.m.: 23 IR 1107; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1332)*

856 IAC 1-3.1-8 Pharmacist intern/extern; minimum/maximum hours of supervision (Repealed)

Sec. 8. *(Repealed by Indiana Board of Pharmacy; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2878)*

856 IAC 1-3.1-9 Pharmacist intern/extern; practical experience affidavits

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 9. The acceptable pharmacist intern or pharmacist extern practical experience time must be verified by practical experience affidavits signed at the termination of each period of practical experience. All such affidavits must list all practical experience time on a calendar week basis showing actual time served each week. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-9; filed Dec 3, 1985, 3:02 p.m.: 9 IR 768; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2877; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-3.1-10 Pharmacist intern/extern; unacceptable experience time (Repealed)

Sec. 10. *(Repealed by Indiana Board of Pharmacy; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)*

856 IAC 1-3.1-11 Out-of-state externship and other practical experience programs; postgraduate requirements; taking the licensure examination before completion of practical experience

Authority: IC 25-26-13-4
Affected: IC 25-26-13-11

Sec. 11. (a) Time accepted for experience gained in approved school supervised practical experience programs in other states successfully completed while enrolled in a professional degree program recognized under IC 25-26-13-11(a)(3) will be credited toward fulfillment of experience hours required under section 7 of this rule. Time accepted for practical experience obtained while not enrolled in a professional degree program and approved under section 6 of this rule may be credited to experience requirements at the board's discretion, whether or not served in Indiana.

(b) A description of the out-of-state practical experience program with the number of hours it contains shall be submitted with the certification for evaluation by the board subject to the following:

(1) Students supplying detailed information on their program at least eight (8) weeks in advance of the board examination date will have their hours evaluated to determine the number that will be accepted toward the prelicensure five hundred twenty (520) hour requirement.

(2) Students not supplying sufficient detailed information on their program or failing to submit the same within eight (8) weeks before the board examination to allow evaluation may take the exam prior to the evaluation of their program. After evaluation, they will be notified of the hours that may be accepted. If sufficient hours are not accepted, licensure will not be granted.

(c) A candidate for licensure who has graduated from an approved school of pharmacy may take the examination before completing the required practical experience hours. However, the candidate will not be licensed as a pharmacist until affidavits are received for the entire practical experience requirement. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-11; filed Dec 3, 1985, 3:02 p.m.: 9 IR 768; errata, 9 IR 1101; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2877; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-3.1-12 Out-of-state practical experience; reciprocity

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 12. Practical experience time served in another state will be accepted and will permit the applicant to take the NAPLEX examination subject to section 11 of this rule if the following requirements are met:

(1) The practical experience time served in such other state meets all requirements of Indiana law and is experience time of the type that is acceptable to the Indiana board of pharmacy (board).

(2) The applicant has a valid intern or apprentice license from the state where the experience is served. Or, if that other state does not require an intern or apprentice license, the applicant must submit certification or an affidavit from the secretary of

the board that state showing that no intern or apprentice license is required.
(Indiana Board of Pharmacy; 856 IAC 1-3.1-12; filed Dec 3, 1985, 3:02 p.m.: 9 IR 769; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2878; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1332)

856 IAC 1-3.1-13 Fraud or misrepresentation in applying for or taking examination
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 13. Any misrepresentation made or any fraud perpetrated in an application for examination, or in the examination, shall be deemed sufficient cause for the refusal of such application, or to complete such examination, and if such misrepresentation or fraud is not discovered until later than at the time of the submission of such application, or until the completion of such examination, it shall be deemed sufficient cause for the dismissal from the examination, or the refusal to grant a certificate, or the revocation of the certificate if already issued, and the fee paid with such application for such examination shall be forfeited; provided, however, that the action of the board shall be subject to the law in force with respect to the denial of a license or permit on application. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-13; filed Dec 3, 1985, 3:02 pm: 9 IR 769; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

Rule 4. Reciprocity

856 IAC 1-4-1 License transfer
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. All applicants for license transfer registration must submit their application, with a certified photograph of the applicant and if necessary a copy of their birth certificate attached thereto, and may be requested to appear in person before the Indiana board of pharmacy (board) for a personal interview during a board meeting. An Indiana law examination must be passed before any certificate of licensure will be issued. A practical examination will be administered to the applicant if the board determines that the applicant has not been actively practicing pharmacy in the twelve (12) months preceding the application. Applications for license transfer must be reviewed and approved at a board meeting prior to examination and prior to the applicant's board requested personal appearance. *(Indiana Board of Pharmacy; Reg 4, Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119; filed Dec 3, 1985, 3:02 p.m.: 9 IR 769; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2878; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1333)*

856 IAC 1-4-2 Application forms
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 2. All applicants applying for license transfer in Indiana are required to make application on the official application blanks issued by the National Association of Boards of Pharmacy. *(Indiana Board of Pharmacy; Reg 4,Sec 2; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1333)*

856 IAC 1-4-3 Restoration of Indiana certification by reciprocity (Repealed)

Sec. 3. *(Repealed by Indiana Board of Pharmacy; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2878)*

856 IAC 1-4-4 Qualifications of applicants for license transfer
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 4. Applicants for license transfer will be admitted to Indiana only if their qualifications for licensure, possessed at the time of their original registration in the state from which they came, were equal to the requirements of Indiana at that time. *(Indiana*

Board of Pharmacy; Reg 4,Sec 4; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 120; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1333)

Rule 5. Recognition of Accredited Schools

856 IAC 1-5-1 Recognition of accredited schools or colleges (Repealed)

Sec. 1. *(Repealed by Indiana Board of Pharmacy; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)*

Rule 6. Drugstores, Pharmacies, Apothecary Shops (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Jun 20, 2001, 3:59 p.m.: 24 IR 3651)

Rule 6.1. Drugstores, Pharmacies, Apothecary Shops

856 IAC 1-6.1-1 Pharmacy equipment; lack of access between adjacent pharmacies

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 1. (a) In addition to the requirements of IC 25-26-13-18, the qualifying pharmacist for each pharmacy issued a permit by the board shall be responsible for all decisions concerning the additional fixtures, facilities, and equipment needed by the pharmacy to operate properly in compliance with the law regulating pharmacies. In making those decisions, the qualifying pharmacist shall consider minimum health, safety, and security measures as well as the type and scope of practice, the patient's needs, and the laws and rules that apply.

(b) If requested by a representative of the Indiana board of pharmacy (board), the qualifying pharmacist shall justify, in writing, all decisions made under this rule.

(c) The board shall determine whether minimum health, safety, and security measures have been satisfactorily met by an applicant for a pharmacy permit before the permit is issued or at any time the permit is in effect.

(d) If the board determines that a pharmacy does not meet the requirements of IC 25-26-13-18 and this rule, it will identify and notify the qualifying pharmacist of the deficiencies. The qualifying pharmacist shall correct or cause to be corrected the deficiencies identified within thirty (30) days of notification by the board of the noncompliance.

(e) Failure to timely correct the deficiencies identified is grounds for denial or revocation of a permit.

(f) To assure that no pharmacy is left unattended by a pharmacist while that pharmacy is in operation, no means of access may be constructed or maintained between adjacent pharmacies. *(Indiana Board of Pharmacy; 856 IAC 1-6.1-1; filed Jun 20, 2001, 3:59 p.m.: 24 IR 3651)*

Rule 7. Pharmacy Permits

856 IAC 1-7-1 Change of pharmacy ownership

Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 1. In case of change of ownership of a pharmacy the original permit becomes void and must be returned, by the new owner, with application to the Board of Pharmacy for a new permit. *(Indiana Board of Pharmacy; Reg 7,Sec 1; filed Jun 18, 1962, 10:00 am: Rules and Regs. 1963, p. 121; readopted filed Sep 14, 2001, 3:04 p.m.: 25 IR 532; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-7-2 Application for permit to conduct pharmacy

Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 2. All applications for a permit to conduct a pharmacy will require the action of at least a quorum of the Board. *(Indiana Board of Pharmacy; Reg 7,Sec 2; filed Jun 18, 1962, 10:00 am: Rules and Regs. 1963, p. 121; readopted filed Sep 14, 2001, 3:04 p.m.: 25 IR 532; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-7-3 Relocation of pharmacy

Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11; IC 25-26-13-18

Sec. 3. To be eligible for relocation of a pharmacy an applicant must show to the satisfaction of the board that the requirements for the eligibility for a pharmacy permit as set out in IC 25-26-13-18 will be met. Prior to relocating a pharmacy the proprietor shall file an application, on a form prescribed and furnished by the board, setting out all information so requested on such form. Prior to moving a pharmacy, after receipt of board approval, the permit holder shall submit the premises to a qualifying inspection by a representative of the board. *(Indiana Board of Pharmacy; Reg 7, Sec 3; filed Jun 18, 1962, 10:00 am: Rules and Regs. 1963, p. 121; filed Dec 3, 1985, 3:02 pm: 9 IR 770; readopted filed Sep 14, 2001, 3:04 p.m.: 25 IR 532; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-7-4 Licensed pharmacist required for each pharmacy

Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 4. Every application for a permit to operate a pharmacy must set forth the name of the pharmacist, licensed by the Indiana board of pharmacy, who will be in full responsible charge for the legal operation of the pharmacy under said permit. Any person, firm, corporation, co-partnership or association owning or operating more than one pharmacy must secure a permit for each such pharmacy and no single registered pharmacist shall be permitted to qualify for more than one store. Provided, however, nothing in this regulation shall be construed to apply to the ownership of such pharmacy but shall apply only to the issuance of permits for the operation of such pharmacy. *(Indiana Board of Pharmacy; Reg 7, Sec 4; filed Jun 18, 1962, 10:00 am: Rules and Regs. 1963, p. 122; filed Dec 3, 1985, 3:02 pm: 9 IR 770; readopted filed Sep 14, 2001, 3:04 p.m.: 25 IR 532; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-7-5 Pharmaceutical consultation service for extended care facilities; notice to board (Expired)

Sec. 5. *(Expired under IC 4-22-2.5, effective January 1, 2003.)*

856 IAC 1-7-6 Consulting pharmacist and dispensing pharmacist; definitions (Expired)

Sec. 6. *(Expired under IC 4-22-2.5, effective January 1, 2003.)*

856 IAC 1-7-7 Duties of consulting pharmacist (Expired)

Sec. 7. *(Expired under IC 4-22-2.5, effective January 1, 2003.)*

Rule 8. Known Pharmaceutical Manufacturer and Manufacturer–Definition

856 IAC 1-8-1 Known pharmaceutical manufacturer; definition (Repealed)

Sec. 1. *(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)*

856 IAC 1-8-2 "Manufacturer" defined (Repealed)

Sec. 2. *(Repealed by Indiana Board of Pharmacy; filed Feb 11, 1981, 9:05 am: 4 IR 379)*

Rule 9. Application for Prohibited Drugs (Repealed)
(Repealed by Indiana Board of Pharmacy; filed Feb 11, 1981, 9:05 am: 4 IR 379)

Rule 10. Non-Drug Products (Repealed)
(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 11. Toxic Preparations (Repealed)
(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 12. Poisons (Repealed)
(Repealed by Indiana Board of Pharmacy; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)

Rule 13. General Definitions

856 IAC 1-13-1 Calendar week (Repealed)

Sec. 1. *(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)*

856 IAC 1-13-2 "Be in personal attendance" defined (Repealed)

Sec. 2. *(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)*

856 IAC 1-13-3 "Prescription department closed" closing hours; electronic monitoring; applicability
Authority: IC 25-26-13-4
Affected: IC 25-26-13-10; IC 25-26-13-19

Sec. 3. (a) This section and section 4 of this rule implement IC 25-26-13-19 concerning board approval for Type I and Type VI pharmacies to be opened to the general public without a pharmacist on duty. This section and section 4 of this rule apply only in situations where the entire area of the business is licensed as a pharmacy. This section, section 4 of this rule, and IC 25-26-13-19 do not apply where the only area of a business licensed as a pharmacy is the prescription department.

(b) The following definitions apply throughout this section:

(1) "Absence of pharmacist" means those periods when the prescription department is closed and secured and the pharmacist is not present in the pharmacy.

(2) "Electronic monitoring system" means a system having the ability by light beam, heat, motion, or other electronically activated method to detect the presence of unauthorized persons or instrumentalities in a given area, and relay or report that detection as described in this section.

(3) "Prescription department" means that area of the pharmacy where the legend drugs, devices, and other merchandise or items which can only be dispensed or delivered by a pharmacist are located and which must be secured in the absence of the pharmacist.

(4) "Reasonable barrier" means an obstruction or barricade that blocks or impedes the entry into the area by an ordinary person, and includes, but is not limited to, a latched or locked gate of sufficient height and construction that an ordinary person cannot breach the barrier and/or violate the space being monitored without detection.

(5) "Secured" means either of the following:

(A) An area is completely enclosed as to its perimeter, from floor to ceiling, and locked.

(B) Through installation of reasonable barriers, an area not readily accessible which is monitored by a board approved electronic monitoring system covering all portions of the secured areas.

(c) Before a pharmacy may be open to the general public without a pharmacist on duty, the pharmacy must file an application with the board and have it approved by the board under IC 25-26-13-19. The pharmacy must abide by the closing hours designated in the application. Any change from the hours as stated in the application must be submitted in writing to the board.

(d) Under IC 25-26-13-19, a prescription department may be locked or secured while the remainder of the pharmacy remains

open to the public if the following criteria are met:

(1) The prescription department is constructed in such a manner or located in such an area that reasonable barriers are in place which prevent the easy and/or quick access to legend drugs and other articles which are in the prescription department. These barriers may be doors or other obstacles as the occasion requires.

(2) The prescription department, if not secured and locked as described in subsection (b)(5)(A), must be secured and monitored by a board approved electronic monitoring device that provides the following:

(A) On-site audible alarm that is clearly and continuously audible at all points within the pharmacy.

(B) Off-site audible or visual alarm that is continuously monitored at all times that the pharmacy remains open while the prescription department is closed and secured.

(3) Any violation or breach of the secured area shall be duly recorded by the qualifying pharmacist of the pharmacy and by the off-site security monitoring agency and reported to the board within seventy-two (72) hours of the violation or breach. This report shall include the nature of the violation or breach.

(4) Facilities monitored electronically must provide for backup power for the eventuality that there is an electronic power failure for any reason. Such backup power shall be capable of continuing the monitoring for a period of no less than thirty-six (36) hours.

(5) The electronic monitoring system shall be activated and inactivated only by key or combination. Alarms which have been triggered shall only be reset and/or reactivated by a pharmacist. The key or combination shall only be in the possession or knowledge of a pharmacist. Reasonable exceptions shall be made to this for security system operators. However, in no case shall a security system operator have access to the secured area without the presence of a pharmacist. Such exceptions shall be listed in the application under this section and shall be subject to approval by the board.

(e) Under IC 25-26-13-10(b), the board may revoke or limit the privilege to be open to the general public without a pharmacist on duty if the pharmacy violates this section or section 4 of this rule. *(Indiana Board of Pharmacy; Reg 13, Sec 3; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 124; filed May 15, 1992, 5:00 p.m.: 15 IR 2246; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-13-4 Record of hours open without a pharmacist on duty

Authority: IC 25-26-13-4; IC 25-26-13-19
Affected: IC 25-26-13-4; IC 25-26-13-19

Sec. 4. The pharmacist shall maintain a record stating any hours that the pharmacy has been open for business without having a pharmacist on duty if those hours vary from the hours listed in the application under section 3(c) of this rule. Entries in this written record shall be made in ink of the time the pharmacist is absent. The written record shall be maintained in the pharmacy and shall be available for examination by members of the board or their inspectors for a period of not less than two (2) years from the date of the last entry in the record. *(Indiana Board of Pharmacy; Reg 13, Sec 4; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 125; filed May 15, 1992, 5:00 p.m.: 15 IR 2247; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-13-5 Legend drugs (Repealed)

Sec. 5. *(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)*

Rule 14. Physical Inventory of Merchandise (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 15. Pharmacists' Notification of Termination

856 IAC 1-15-1 Pharmacist leaving employ of pharmacy; notice to board; application to qualify permit

Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-18

Sec. 1. If a qualified pharmacist, who, having upon the basis of his or her qualifications caused a pharmacy permit to be

granted to any person, firm, corporation or copartnership desiring to operate, maintain, open or establish a pharmacy should leave the employ of such pharmacy, he or she shall immediately notify the Indiana board of pharmacy (board) and the owner shall file an application with the board to qualify the permit with another pharmacist. *(Indiana Board of Pharmacy; Reg 15, Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 125; filed Dec 3, 1985, 3:02 p.m.: 9 IR 771; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1333)*

Rule 16. New Pharmacist (Repealed)
(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 17. Practice of Pharmacy (Repealed)
(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 18. Narcotic License (Repealed)
(Repealed by Indiana Board of Pharmacy; filed Feb 11, 1981, 9:05 am: 4 IR 379)

Rule 19. Adoption by Reference of U.S. Federal Rules Pertaining to Narcotics (Repealed)
(Repealed by Indiana Board of Pharmacy; filed Feb 11, 1981, 9:05 am: 4 IR 379)

Rule 20. Violations and Penalties

856 IAC 1-20-1 Prohibitions
Authority: IC 25-26-13-4
Affected: IC 25-26; IC 35-48

Sec. 1. A pharmacist licensed to practice pharmacy under IC 25-26-13-1 through 25-26-13-29, or a pharmacist extern or a pharmacist intern licensed under IC 25-26-13-10, as a part of the responsibility, to not knowingly violate the Indiana board of pharmacy's (board's) standards for the competent practice of pharmacy shall not do the following:

(1) Violate the Uniform Indiana Controlled Substances Act found at IC 35-48-1-1 through 35-48-4-14, as amended up to and including January 1, 1983, or any of the rules promulgated by the board under the authority of the Uniform Indiana Controlled Substances Act, which were effective by January 1, 1983, insofar as such violation would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.

(2) Violate the Indiana Legend Drug Act found at IC 16-6-8-1 through 16-6-8-9 *[IC 16-6 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]*, as amended up to and including January 1, 1983, insofar as such violation would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.

(3) Violate IC 16-1-30-1 through IC 16-1-30-19 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]*, as amended to and including January 1, 1983, which deal with adulterated and misbranded drugs or devices, or any rules promulgated by the board under the authority of IC 16-1-30-1 through IC 16-1-30-19 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]*, which were effective as of January 1, 1983, insofar as such violation would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.

(4) Violate 21 U.S.C. 801 through 21 U.S.C. 1191, as amended, up to January 1, 1983, which deal with drug abuse and any of the rules and regulations promulgated under the authority of said Title and Sections as of January 1, 1983, insofar as such violations would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.

(5) Violate the Federal Food, Drug, and Cosmetic Act, which is found at 21 U.S.C. 301 through 21 U.S.C. 392, as amended, up to January 1, 1983, or any rules or regulations promulgated under the authority of the said act as of January 1, 1983, insofar as such violation would pertain to the sale of drugs or devices in Indiana as defined by IC 25-26-13-2.

(6) Violate Executive Proclamations of the President of the United States, which were effective by January 1, 1983, which pertain to the sale of drugs or devices in Indiana as defined by IC 25-26-13-2.

(7) Sell, as defined in IC 25-26-13-2, controlled substances or legend drugs with or without prescription, where such sale or distribution is not in good faith and enables the person to whom the sale is made to supply or divert the controlled substances or legend drugs in an unlawful manner. The sale or distribution of controlled substances or legend drugs in unusually large

amounts and within an unusually short period of time to the same individual is considered to be against the public welfare, health and safety and may be determined to be a sale or distribution not in good faith.

(8) Sell, as defined in IC 25-26-13-2, to the public any drugs, biologicals, medicinal substances, or devices when such pharmacist knows such drugs, biologicals, medicinal substances, or devices to be forgeries or a counterfeit product or beyond the manufacturer's expiration date.

(9) Aid or abet in the practice of a pharmacy a person not having a license to practice as a pharmacist in Indiana.

(10) Practice pharmacy in such a manner as to amount to incompetency or negligence in the sale or dispensation of legend drugs as defined in the Indiana Legend Drug Act under IC 16-6-8-2 *[IC 16-6 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]* or controlled substance as defined in the Uniform Controlled Substances Act of 1973, under IC 35-48-1-1.

(11) Violate the act regulating the practice of pharmacy in Indiana, which is codified at IC 25-26-13-1 through IC 25-26-13-29 as amended up to and including January 1, 1983, or any of the rules promulgated by the board under the authority of the said act, which were effective by January 1, 1983.

(Indiana Board of Pharmacy; Reg 20; filed Nov 17, 1978, 2:06 p.m.: 2 IR 63; filed Jul 28, 1983, 9:01 a.m.: 6 IR 1745; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1333)

Rule 21. Resale of Returned Substances

856 IAC 1-21-1 Resale of returned substances

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 1. (a) This section implements and interprets IC 25-26-13-25(h) concerning the resale or redistribution of medications.

(b) For a medication to have been properly stored and securely maintained according to sound pharmacy practices, the storage and administration of medications in the institutional facility must be under the immediate control of licensed nursing personnel.

(c) If the medication was originally packaged by the dispensing pharmacy, it cannot be resold or redistributed unless:

(1) the medication has been repackaged into unit-dose packaging using packaging materials that meets Class A or Class B standards, found in the United States Pharmacopeia (U.S.P.), page 1574, published by the United States Pharmacopeia, 22nd Revision, January 1, 1990, United States Pharmacopeia Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, which standards are incorporated herein by reference; and

(2) the repackaging process complies with the standards as found in the "Proper Treatment of Products Subjected to Additional Manipulations, Section 1191" of the United States Pharmacopeia, page 1705, 22nd Revision, 1990, which section is incorporated herein by reference.

(d) A medication repackaged under the provisions of subsection (c) shall be labeled with an expiration date of not greater than one (1) year until the manufacturer's expiration date, whichever is earlier. *(Indiana Board of Pharmacy; Reg 21, Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 128; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1391; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1334)*

Rule 22. Narcotics–Defined (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 23. Dispensing of Dangerous Drugs

856 IAC 1-23-1 Dispensing of dangerous drugs

Authority: IC 25-26-13-4
Affected: IC 16-42-22; IC 25-26-13-4; IC 25-26-13-11

Sec. 1. In the sale or dispensing of any prescription drug or narcotic, the pharmacist shall be required to affix to the immediate container in which such prescription drug or narcotic is delivered a label bearing the following information:

(1) The name, address, and telephone number of the establishment from which such drug was sold.

(2) The date on which the prescription for such drug was filled.
(3) The number of such prescription as filed in the prescription files of the pharmacy where the prescription was filled.
(4) The name of the practitioner who prescribed such drug.
(5) The name of the patient, and if such drug was prescribed for an animal, a statement of the species of the animal and the owner's name.
(6) The directions for use of the drug as contained in the prescription.
(7) The name of the drug (trade or generic, or both) in compliance with the Generic Drug Law found in IC 16-42-22.

(Indiana Board of Pharmacy; Reg 23,Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 129; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1335)

Rule 24. Hospital Pharmacies (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Jun 8, 1982, 10:04 am: 5 IR 1420)

Rule 25. Internship for Apprentice Pharmacists (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 26. Continuing Professional Education

856 IAC 1-26-1 Continuing professional education; general requirements; definitions

Authority: IC 25-26-13-4
Affected: IC 25-1-9-3; IC 25-26-13-14

Sec. 1. (a) The following definitions apply throughout this rule:
(1) "Continuing professional education" or "continuing education" means accredited postlicensure professional educational experience derived from participation in postgraduate studies, institutes, seminars, lectures, conferences, workshops, and such other forms of educational experiences so as to maintain the professional competency of the practice of pharmacy, improve pharmacy professional skills, and preserve pharmaceutical standards for the purpose of the protection of the health and welfare of the citizens of Indiana.
(2) "Hours" means measurement of value applied to a particular accredited continuing pharmacy educational activity as assigned by the Indiana board of pharmacy (board) relative to maintaining the competency of a pharmacist.
(3) "Contact hour" means not less than fifty (50) nor more than sixty (60) minutes of clock time participating in a continuing education program.
(4) "Continuing education unit" or "CEU" means ten (10) contact hours of continuing education credit.
(5) "Approved by ACPE" means pharmacy continuing education providers that meet the requirements of "The ACPE Continuing Education Provider Approval Program Criteria for Quality and Interpretive Guidelines" as published by the American Council on Pharmaceutical Education, Inc., Chicago, Illinois on July 1991.
(b) In order to qualify for licensure renewal, a pharmacist must meet the continuing professional education requirements as follows:
(1) Thirty (30) hours (three (3) CEUs) of continuing education as required by this rule shall be required each biennium.
(2) No hours may be carried forward from one (1) biennium to another. However, if a pharmacist fails to meet the requirements of this rule during the biennial period, the pharmacist may earn and report sufficient hours during a succeeding biennium and apply the continuing education hours retroactively to the previous biennium as if they had been earned in that previous biennium in order to qualify for renewal of the pharmacist's license. In the event a pharmacist applies credits to a previous biennium for the reasons stated in this section, those credits may not be used for any other biennium.
(3) All continuing education program hours from sponsors not approved by ACPE must be evaluated and accepted by the board.
(4) Continuing education biennium shall be that time period consisting of January 1 of all even-numbered years through December 31 of the following odd-numbered year.
(c) Accredited continuing education hours may be compiled in the following ways if the sponsor grants the participant a certificate of completion:

(1) Cassette and audio-visual presentation.
(2) In-company professional seminars.
(3) Accredited school of pharmacy continuing education programs.
(4) Postgraduate courses in pharmaceutical sciences.
(5) Correspondence courses.
(6) Programs granted continuing education credit by other states.
(7) Continuing education television series.
(8) Programs sponsored by professional groups in public health provider services.
(9) Professional society and association sponsored program.
(10) Approved business, management, and computer courses.
(11) Programs of sponsors approved by ACPE.

(d) Accredited continuing education hours may be compiled from other programs and experiences if they are evaluated and accepted by the board as meeting the definition of continuing professional education as found in subsection (a)(1).

(e) As provided in subsection (b)(3), continuing education sponsors (hereinafter referred to as sponsors) are responsible for submitting continuing education programs to the board for approval in addition to the following:

(1) A sponsor shall be any person, school, association, or corporation who develops a continuing education program.
(2) The continuing education program must receive approval of the board for final acceptance.
(3) If a sponsor wishes to notify prospective participants in advance of the value (in hours or in CEUs) of a program, the content of the program shall be submitted to the board for evaluation. If the sponsor does not submit the content for evaluation, the sponsor shall note in all material relevant to the program that it has not been evaluated and the hours of credit listed are subject to review by the board.
(4) Sponsors shall receive written notice from the board for approval or disapproval from the board. Approved programs shall be given an identification number stating the year and hourly value.
(5) Program changes must be made to and accepted by the board or the evaluation and acceptance of the program becomes null and void.
(6) Continuing education credit may be granted only once for each program to any individual participant.
(7) Any member of the board shall have the right to attend and participate in any continuing education program.
(8) Programs may be evaluated after presentation or participation if a written request is made to the board within ninety (90) days of the date of presentation.
(9) Sponsors shall retain a file of participants' program completion for four (4) years.
(10) When applying to the board for credit, sponsors shall supply the following information on the application for continuing education course approval, supplied by the board:

(A) Name and address of applicant.
(B) Program title.
(C) Location, date, and time of program.
(D) Sponsoring organization.
(E) Type of program.
(F) Name and qualification of each speaker.
(G) Three (3) learning objectives for the program.
(H) Contact hours of the course.
(I) Method for evaluating the program.

(f) Pharmacists licensed with the board (hereinafter called participants) have the following responsibilities:

(1) Obtain a minimum of thirty (30) hours of continuing education per biennium unless first licensed during the biennium which would make those newly licensed individuals subject to subdivision (5):

(A) a maximum of one-fifth ($^{1}/_{5}$) of the total hours may be business, management, or computer courses;
(B) at least four-fifths ($^{4}/_{5}$) of the total hours must be pharmacy practice related; and
(C) at least one-half (½) of the total hours must be provided by sponsors approved by ACPE.

(2) Report program name, identification number, and approved hours of continuing education to the board at the time of license renewal.
(3) Retain a file of certificates of completion for four (4) years from the end of the biennium for which the continuing

education applied in order to provide copies of certificates upon request for the board's periodic audit of continuing education compliance.

(4) Earn one and one-fourth (1.25) hours of continuing education credit for each month or part of a month from date of licensure until the end of the biennium in which licensure originates if the pharmacist becomes licensed during the biennium. However, a pharmacist who becomes newly licensed for the first time in any state in the last six (6) months of the biennium shall not be required to complete any continuing education for the biennium.

(5) Continuing education hours may be transferred from another state to Indiana if the transfer state recognizes Indiana continuing education hours.

(g) Failure to comply with any one (1) or all of the provisions of this rule while continuing to hold a license as a pharmacist in Indiana shall constitute professional incompetence by failing to keep abreast of current professional theory or practice under IC 25-1-9-3(a)(4)(B) and the pharmacist is subject to discipline under IC 25-1-9. *(Indiana Board of Pharmacy; Reg 29; filed Mar 1, 1974, 3:05 p.m.: Rules and Regs. 1975, p. 516; filed Oct 26, 1984, 3:26 p.m.: 8 IR 212; filed Jan 21, 1994, 3:00 p.m.: 17 IR 1096, eff Jan 1, 1994 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #93-152 was filed Jan 21, 1994.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1335)*

Rule 27. Fee Structure

856 IAC 1-27-1 Fees

Authority: IC 25-1-8-2; IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. (a) The fee for licensure by examination as a pharmacist shall be an administrative fee of one hundred dollars ($100).

(b) The fee for licensure as a pharmacist from another state by reciprocity (also known as license transfer) and without a full examination shall be one hundred dollars ($100).

(c) The fee for taking or retaking the state jurisprudence examination or the practical examination shall be twenty-five dollars ($25).

(d) The fee for the renewal of a license as a registered pharmacist shall be seventy-five dollars ($75) per year. The board shall collect an additional five dollars ($5) per year from each individual who renews a pharmacist license to fund a program to assist impaired pharmacists.

(e) The fee for a license as a pharmacist intern/extern shall be ten dollars ($10). The renewal fee for such a license shall be ten dollars ($10).

(f) The fee for both an initial application and renewal to operate an in-state pharmacy shall be one hundred dollars ($100) per year. When there is a change of ownership, a new permit must be obtained, and the fee shall be fifty dollars ($50). When there is a change of location, the current permit is updated and the fee is fifty dollars ($50).

(g) The fee for certificate of qualifications, registration, and grades in any application for reciprocity to another state shall be ten dollars ($10).

(h) There will be no fee for a duplicate pharmacy license or duplicate pharmacist pocket license.

(i) The fee for a duplicate pharmacist's wall certificate shall be ten dollars ($10).

(j) The fee for a complete compilation of the pharmacy laws shall be ten dollars ($10).

(k) The fee for both an initial registration and renewal registration of a nonresident pharmacy shall be one hundred dollars ($100) per year. *(Indiana Board of Pharmacy; Reg 29; filed Aug 30, 1977, 8:25 a.m.: Rules and Regs. 1978, p. 660; filed Mar 5, 1985, 2:42 p.m.: 8 IR 802; filed Nov 13, 1985, 3:08 p.m.: 9 IR 772; filed Apr 30, 1986, 9:43 a.m.: 9 IR 2204; filed Sep 8, 1987, 2:30 p.m.: 11 IR 95; filed Jul 24, 1991, 2:45 p.m.: 14 IR 2238; filed Jun 6, 1996, 9:00 a.m.: 19 IR 3106; filed May 29, 1998, 11:56 a.m.: 21 IR 3931; filed Aug 5, 1998, 3:48 p.m.: 21 IR 4535; filed Apr 16, 2002, 9:03 a.m.: 25 IR 2739) NOTE: Renumbered Reg 30 by 1978 Amendment.*

Rule 28. Institutional Pharmacies (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1643)

Rule 28.1. Institutional Pharmacies and Pharmacy Services

856 IAC 1-28.1-1 Definitions

Authority: IC 25-26-13-4
Affected: IC 16-42-19-5; IC 25-6-3-7; IC 25-26-13

Sec. 1. In addition to the definitions in IC 25-26-13-2 and for purposes of this rule, the following definitions apply throughout this rule:

(1) "Cabinet" includes a mechanical storage device for dispensing drugs. The term means a locked or secured enclosure located outside the pharmacy licensed area:

(A) to which only specifically authorized personnel may obtain access by key or combination available only to those authorized persons by:

(i) security code;

(ii) password; or

(iii) other method of positively identifying an individual; and

(B) that is sufficiently secure to deny access to unauthorized persons.

(2) "Cognitive services" means those acts and operations related to a patient's drug therapy that are judgmental in nature, based on knowledge, and derived from empirical factual information.

(3) "Consultant pharmacist" means a pharmacist licensed pursuant to IC 25-26-13-11 and who engages in the practice of pharmacy in or for long term care facility or other residential patients, other than as a supplying pharmacist.

(4) "Consulting" means the provision of nonsupply related cognitive services that include, but are not necessarily limited to, the following:

(A) Drug regimen review as defined in IC 25-26-13-2.

(B) Provision of advice and counsel on drugs, the selection and use thereof to the facility, the patients therein, the health care providers of the facility regarding the appropriateness, use, storage, handling, administration, and disposal of drugs within the facility.

(C) Participation in the development of policies and procedures for drug therapy within the institution, including storage, handling, administration, and disposing of drugs and devices.

(D) Assuring the compliance with all applicable laws, rules, and regulations.

(E) Provision of educational and drug information sources for the education and training of the facility health care professionals.

(F) Accepting responsibility for the implementation and performance of review of quality-related or sentinel events as defined in this rule.

(5) "Emergency drugs" means those drugs that:

(A) may be required to meet the immediate therapeutic needs of patients; and

(B) are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such drugs from other sources.

(6) "Institutional facility" means any health care facility whose primary purpose is to provide a physical environment for patients to obtain health care services, except those places where practitioners, as defined by IC 16-42-19-5, who are duly licensed, engage in private practice and pharmacies licensed under IC 25-26-13-17.

(7) "Institutional pharmacy" means that portion of an institutional facility where pharmacy is practiced and is:

(A) the location of the selection, compounding, production, sale, storage, and distribution of drugs, devices, and investigational or new drugs used in the diagnosis and treatment of injury, illness, and disease pursuant to drug orders and prescriptions by practitioners; and

(B) licensed with the board under IC 25-6-3-7.

(8) "Performance improvement program" means a continuous, systematic review of key medication use processes to identify, evaluate, and improve medication use and patient care.

(9) "Pharmacist in charge" (by whatever title, for example, "pharmacy manager", "pharmacy director", or "director of pharmacy") means the pharmacist who directs the activities of the institutional pharmacy and who is, as such, responsible for:

(A) all activities of the institutional pharmacy; and

(B) meeting the requirements of:

(i) IC 25-26-13;

(ii) the rules of the board; and
(iii) any federal requirements pertaining to institutional pharmacies.

The qualifying pharmacist may, depending on the circumstances, also be the pharmacist in charge, though the pharmacist in charge is not required to be the qualifying pharmacist.

(10) "Policy and procedure manual" means a written document containing the agreed-to institutional rules of operation and methodology for the effective delivery of pharmacy services.

(11) "Qualifying pharmacist" means the pharmacist who accepts responsibility for the operation of a pharmacy as defined in IC 25-26-13-2 and whose name is listed on the pharmacy permit granted under IC 25-26-13-17.

(12) "Quality-related event" means the inappropriate provision of pharmaceutical services whether or not resulting in an adverse health incident, including the following:

(A) A variation from the practitioner's order, including, but not limited to, the following:
(i) Dispensing an incorrect drug.
(ii) Dispensing an incorrect drug strength.
(iii) Dispensing an incorrect dosage form.
(iv) Dispensing a drug to a wrong patient.
(v) Providing inadequate or incorrect packaging, labeling, or directions.
(vi) Failing to provide an ordered drug.

(B) A failure to identify and manage:
(i) overutilization or underutilization;
(ii) therapeutic duplication;
(iii) drug-disease contraindications;
(iv) drug-drug interactions;
(v) incorrect drug dosage or duration of therapy;
(vi) drug-allergy interactions; or
(vii) clinical abuse and/or misuse.

(13) "Reversible condition" means a condition that requires intervention to resolve in a reasonable time.

(14) "Sentinel event" means an unexpected occurrence involving serious adverse effect, such as disability, life threatening condition, prolonged hospitalization, or death in a patient resulting from medication use.

(15) "Supplying pharmacist" means that pharmacist licensed in the state where the pharmacist is practicing and who is practicing in a supplying pharmacy (as defined in this rule) and who accepts responsibility for all aspects the drugs and devices sold (as defined in IC 25-26-13-2) or dispensed to a facility.

(16) "Supplying pharmacy" means a pharmacy licensed in the state where the pharmacy is located and which provides drugs and devices to patients in long term care or other facilities where patients reside.

(17) "Temporary condition" means a condition that resolves in a reasonable time without intervention.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-1; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1636)

856 IAC 1-28.1-2 Purpose

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 2. The purpose of this rule is to set forth the responsibilities of pharmacists and pharmacies serving institutional and home health care patients. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-2; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1637)*

856 IAC 1-28.1-3 Applicability

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 3. This rule is applicable to pharmacies located:

(1) within institutional facilities as defined in section 1 of this rule and classified as Type II pharmacies in IC 25-26-13-17; and

(2) outside institutional facilities that serve institutionalized patients who are classified as Type III and Type VI pharmacies as in IC 25-26-13-17.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-3; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1637)

856 IAC 1-28.1-4 Pharmacist in charge; responsibilities

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 4. The pharmacist in charge or an appropriate designee shall:

(1) be responsible for establishing and carrying out a performance improvement program as defined in section 1 of this rule; and

(2) develop or be responsible for development of a policies and procedures manual that shall be of sufficient scope and detail that pharmacists practicing in the institutional pharmacy will be able to practice effectively and safely.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-4; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1637)

856 IAC 1-28.1-5 Policies and procedures manual

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 5. (a) The pharmacist in charge shall develop or be responsible for the development of a policies and procedures manual that shall be of sufficient scope and detail that pharmacists practicing in the institutional pharmacy will be able to practice effectively and safely.

(b) The manual required in this section shall be available for inspection by a member of the board or its representative.

(c) The policies and procedures manual shall contain, at a minimum, the following:

(1) Provisions for a continuous quality improvement committee that shall be comprised of staff members of the pharmacy, including, but not necessarily limited to, the following:

(A) Pharmacists.
(B) Pharmacist interns or externs.
(C) Pharmacy technicians.
(D) Clerical or support staff.
(E) Other persons deemed necessary by the qualifying pharmacist.

(2) Provisions for the pharmacist in charge or designee to ensure that the committee conducts a review of quality related events at least every three (3) months.

(3) A process to record, measure, assess, and improve quality of patient care.

(4) The procedure for reviewing quality related or sentinel events.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-5; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1637)

856 IAC 1-28.1-6 Personnel

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 6. The qualifying pharmacist and/or the pharmacist in charge shall develop and implement, or cause to be developed and implemented, policies and procedures that specify duties to be performed by pharmacy technicians and other ancillary personnel.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-6; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1638)

856 IAC 1-28.1-7 Pharmacist's duties

Authority: IC 25-26-13-4
Affected: IC 16-42-19-3; IC 25-26-13-2; IC 25-26-13-31; IC 25-26-16

Sec. 7. (a) Pursuant to authority granted in IC 25-26-13-2 and IC 25-26-13-31, the duties of the pharmacists practicing in the

institutional pharmacy include, but are not limited to, the requirements in this section.

(b) The pharmacist practicing in an institutional pharmacy shall, at a minimum, do the following:

(1) Obtain and maintain patient drug histories and drug profiles.

(2) Perform drug evaluations, drug utilization review, drug regimen review, and drug therapy management under protocol approved by the medical staff of the institution and authorized by IC 25-26-16.

(3) Interpret the drug order written by a practitioner in or transmitted to an institutional facility and either received in or subsequently transmitted to the pharmacy.

(4) Be responsible for checking all drug orders within a maximum of twenty-four (24) hours, including those written during periods when the pharmacy is closed and orders are filled from sources, including emergency kits, drug cabinets, or the pharmacy as authorized under section 8(c) of this rule.

(5) Be responsible for drug product selection of the item that will be used to fill the drug order that may be established either by policy or formulary pursuant to the institution's pharmacy and therapeutics committee or related committee.

(6) Be responsible for determining the legality, completeness, and appropriateness of the drug order and product pursuant to IC 16-42-19-3.

(7) Participate in drug or drug-related research.

(8) Provide counseling, advising, and education of patients, patients' care givers, and health care providers and professionals on issues regarding drugs or drug therapy.

(9) Compound, label, administer, and dispense drugs or devices.

(10) Assess, record, and report quality related events as defined in this rule.

(11) Be responsible for storage and distribution of drugs and devices.

(12) Provide documentation in the medical record of the recommendations made related to the patient's therapeutic response to medication.

(13) Any other duties that shall from time to time be necessary for the proper operation of the institutional pharmacy.

(c) The consultant pharmacist shall, in addition to the duties in subsection (b), provide cognitive services as defined in this rule, including, at a minimum, the following:

(1) Drug regimen reviews as defined in IC 25-26-13-2.

(2) Offer advice and counsel to other health care providers as deemed appropriate regarding the pharmaceutical care of the patient.

(3) Develop or assist in the development of policies and procedures for the legal, safe, and effective means of handling, storing, and disposing of drugs and devices.

(4) Be responsible for assuring the safe and appropriate receipt, labeling, storage, and disposal of all drugs placed outside the pharmacy licensed area in emergency drug kits or other storage devices as authorized by law or rule.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-7; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1638)

856 IAC 1-28.1-8 Absence of pharmacist

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 8. (a) During such times as an institutional pharmacy is closed and unattended by a pharmacist, the drugs may be obtained for patient use as outlined in this section.

(b) Cabinets, including mechanical storage devices for dispensing drugs, are locked or secured enclosures located outside the pharmacy licensed area, to which only specifically authorized personnel may obtain access by key, combination, or security code, password, or other method of positively identifying an individual, and are sufficiently secure to deny access to unauthorized persons. The qualifying pharmacist and/or pharmacist in charge shall, in conjunction with the appropriate committee of the institutional facility, develop inventory listings of the drugs to be included in such cabinets and shall ensure the following:

(1) Such listed drugs, properly labeled, are available therein.

(2) Only prepackaged drugs (meaning that no repackaging is required at the time of removal for an individual patient's use) are available therein, in amounts sufficient for immediate therapeutic requirements for a period not to exceed twenty-four (24) hours.

(3) When drugs are used, a record is made to include a written physician's order or accountability record.

(4) All drugs therein are reviewed by a pharmacist upon return to duty, not to exceed twenty-four (24) hours.

(5) There are written policies, procedures, and forms established to implement the requirements of this subsection.

(c) Whenever any drug is not available from floor supplies or cabinets, as defined in this section, and such drug is required to treat the immediate needs of a patient, such drug may be obtained from the pharmacy in accordance with the requirements of this subsection. One (1) supervisory licensed nurse in any given shift may have access to the pharmacy and may remove drugs there from. The qualifying pharmacist shall require that the removal of any drug from the pharmacy by an authorized nurse be recorded on a suitable form, which includes the name of the drug, strength, amount, date, time, and signature of nurse, and that a copy of the order shall be left with the form.

(d) Requirements for hospital emergency drug boxes, drug carts, emergency kits, emergency drug kits, crash carts, drug kits, or other storage method for emergency drugs are as follows:

(1) Pharmacy policy and procedures shall assure the:

(A) availability;

(B) control; and

(C) security;

of emergency drug carts, drug kits, or drug boxes in the pharmacy and patient care areas.

(2) Procedures shall include the following:

(A) Determination of drugs and quantities of drugs to be included.

(B) Labeling for expiration date.

(C) Process for restocking the cart, kit, or box.

(D) Security measures to prevent unauthorized access.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-8; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1638)

856 IAC 1-28.1-9 Emergency drug kits from Type III and Type VI pharmacies

Authority: IC 25-26-13-4

Affected: IC 25-26-13-17; IC 35-38

Sec. 9. (a) Emergency drug kits supplied by pharmacies with a Type III or Type VI permit shall be in compliance with this section.

(b) All drugs in the emergency kit shall be provided and owned by a single supplying pharmacy.

(c) All drugs in the emergency drug kit shall be selected and approved by a committee whose membership includes, at a minimum, the following:

(1) The facility's consultant pharmacist.

(2) A licensed nurse.

(3) A physician (medical doctor or doctor of osteopathy).

(4) The facility administrator.

(d) The selection process must identify drugs and quantities thereof in the emergency drug kit.

(e) The lists of drugs and quantities included in the emergency drug kit shall be reviewed as required periodically, but no less often than yearly.

(f) Labeling as follows:

(1) The exterior labeling of the emergency drug kit as described in this subsection shall contain, at a minimum, the following:

(A) Drug name (trade name, generic name, or active ingredients).

(B) Drug strength or size, if any.

(C) Quantity included therein.

(D) Expiration date of the kit as defined in this section.

(2) All drugs contained in the emergency drug kit as described in this section shall be labeled, at a minimum, with the following:

(A) Drug name (trade name, generic name, or active ingredients).

(B) Drug strength or size, if applicable.

(C) Name of the manufacturer, packer, or distributor.

(D) Lot number.

(E) Expiration date.

(g) The expiration date of the emergency drug kit, as required in subsection (f)(1)(D) shall be the earliest date of expiration of any of the drugs included in the kit at any time.

(h) All emergency kits subject to this subsection:

(1) shall be stored in a secure area, suitable for the prevention of unauthorized access to or diversion of the drugs therein;

(2) if controlled substances, as defined in IC 35-38, are stored in such a manner as to facilitate periodic reconciliation by the facility nursing staff, that reconciliation shall be recorded in an appropriate manner as determined by the committee described under this section; and

(3) all controlled substances contained in emergency drug kits shall remain the property of the supplying pharmacy and as such shall be included in the pharmacy's biennial inventory as required by 21 CFR 1303.04 and 21 CFR 1301.11.

(i) The nurse responsible for removing drugs from an emergency drug kit shall record or cause to be recorded, in a manner designated under subsection (h)(2), the following minimum information:

(1) Name of the patient.

(2) Name of the drug.

(3) Strength of the drug.

(4) Quantity removed.

(5) Date of removal.

(6) Time of removal.

(j) Removal of a controlled substance in Schedule II pursuant to an oral authorization from a practitioner shall be documented, and the nurse accepting such authorization is responsible for compliance with 856 IAC 2-6-7 regarding prescription requirements for controlled substances in Schedule II.

(k) Removal of a controlled substance in Schedule III, IV, or V, pursuant to an oral authorization from a practitioner, shall be documented, and the nurse accepting such authorization is responsible for compliance with 856 IAC 2-6-12.

(l) Whenever an emergency kit is opened, for any reason, the supplying pharmacy shall be notified in a timely manner, and the pharmacy shall restock, if necessary, and reseal the kit promptly so as to prevent risk of harm to patients of the facility. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-9; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1639)*

856 IAC 1-28.1-10 Security

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 10. The pharmacy shall be capable of being secured against entry by key, combination, code, password, or other method developed that can positively identify an individual so as to prevent access by unauthorized personnel. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-10; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1640)*

856 IAC 1-28.1-11 Performance improvement events, sentinel events, corrective and avoidance measures, review, records, and documentation

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 11. (a) The pharmacist in charge shall, as a part of the pharmacy's performance improvement program, assure or be responsible for assuring that data are collected to:

(1) monitor the stability of existing medication use processes;

(2) identify opportunities for improvement; and

(3) identify changes that will lead to and sustain improvement.

(b) Identification of quality related or sentinel event as defined in section 1 of this rule shall be cause for:

(1) an intensive analysis of causal factors involved in the event; and

(2) plans for corrective actions.

(c) Records of all processes, analysis, and corrective measures instituted involving such pharmacy quality related or sentinel event shall be maintained for a period of not less than two (2) years.

(d) The committee created under section 5(c)(1) of this rule shall, at a minimum, consider the effects on quality of the pharmacy system due to the following:

(1) Staffing levels of both professional and technical personnel.

(2) Workflow.

(3) Use of technology.

(e) Requirements for documentation of performance improvement monitoring of medication use processes, confidentiality of records, summarization, and examination by the board shall be as follows:

(1) Each quality related or sentinel event that occurs, or is alleged to have occurred, as the result of activities involving pharmacy operations, shall be documented in a written or electronic storage record created solely for that purpose.

(2) The quality related or sentinel event shall be:

(A) initially documented by the pharmacist to whom it is first described; and

(B) recorded on the same day of its having been so described to the pharmacist.

(3) Documentation shall include a description of the event that is of sufficient detail to permit analysis of the event.

(4) The pharmacist in charge shall summarize, or cause to be summarized, efforts to improve the medication use process on a semiannual basis.

(5) No patient names or employee names shall be included in this summary report.

(6) This report shall be maintained for a period of not less than two (2) years.

(7) The records created and maintained as a component of a pharmacy performance improvement program are confidential to the extent law permits. However, to assure compliance, the board or its representative may review the policies and procedures manual and a summarization of events described in subsection (b).

(Indiana Board of Pharmacy; 856 IAC 1-28.1-11; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1640)

856 IAC 1-28.1-12 Drug distribution, storage, and accountability

Authority: IC 25-26-13-4

Affected: IC 25-26-13-17

Sec. 12. (a) All drugs and devices in pharmacies located within institutions shall be obtained and used in accordance with written policies and procedures that have been prepared or approved by the qualifying pharmacist or pharmacist in charge and the medical staff who explain the:

(1) selection;

(2) distribution;

(3) storage; and

(4) safe and effective use of:

(A) drugs;

(B) new drugs;

(C) investigational new drugs; and

(D) devices;

in the facility.

(b) The pharmacist in charge of the pharmacy located within an institution shall be responsible for the following:

(1) The safe and efficient:

(A) distribution;

(B) control;

(C) storage; and

(D) accountability;

for all drugs and devices.

(2) The compliance with all applicable Indiana and federal laws and rules.

(c) Labeling requirements are as follows:

(1) All drugs, other than unit-of-use packages, dispensed by an institutional pharmacy, intended for use within the facility, shall be distributed in appropriate containers and adequately labeled so as to identify, at a minimum, the following:

(A) Patient identification.

(B) Brand name or generic name, or both.
(C) Strength, if applicable.
(D) Route of administration.
(E) Quantity.
(F) Pharmacist's initials.
(G) Location of the patient within the institution.

(2) Unit-of-use packages shall contain information to adequately label them, at a minimum, as follows:
(A) Drug name (brand or generic, or both).
(B) Strength, if applicable.
(C) Control number and/or expiration date.

(3) All drugs dispensed by an institutional pharmacy to patients about to be discharged, or temporarily discharged, from institutions with Type III or Type IV permits, shall be labeled with the following minimum information:
(A) Name, address, and telephone number of the institutional pharmacy.
(B) Date and identifying serial number.
(C) Name of patient.
(D) Name of drug and strength, if applicable.
(E) Directions for use by the patient and route of administration.
(F) Name of prescribing practitioner.
(G) Precautionary information if any contained in the prescription.

(d) Requirements for the disposition of discontinued or recalled drugs are as follows:

(1) The qualifying pharmacist or pharmacist in charge shall be responsible for the development and implementation of policies and procedures for the return to the pharmacy of drugs and containers that are:
(A) discontinued, outdated, or recalled; or
(B) in containers with worn, illegible, or missing labels;
for proper disposition.

(2) The qualifying pharmacist or pharmacist in charge or his or her designee shall make proper disposition of such drugs at the storage site.

(e) The qualifying pharmacist or pharmacist in charge shall ensure that drugs are dispensed from the institutional pharmacy only upon authorized practitioner's:
(1) written orders;
(2) direct copies;
(3) facsimiles thereof; or
(4) electronically transmitted by other means and printed or displayed appropriately.

(f) Accountability requirements are as follows:

(1) The qualifying pharmacist or pharmacist in charge of an institutional pharmacy shall ensure that policies and procedures documenting the trail of:
(A) controlled substances; and
(B) such other drugs as may be specified by the appropriate committee of the institutional facility, from ordering and receiving by the pharmacy through administration or wastage of drug at the patient level.

(2) The qualifying pharmacist or pharmacist in charge shall be responsible for review of this process on a continual basis by review of:
(A) proofs-of-use documentation; or
(B) other electronic documentation methodology.

(3) At a minimum, the documentation process shall be able to identify the following:
(A) The name of the drug.
(B) The dose.
(C) The patient's name.
(D) The date and time of administration to the patient.
(E) The identification of the individual administering.
(F) The record of aliquot portion destroyed, if any, and identification of witness.

(g) All records and reports that are required for pharmacy functions shall be maintained according to policies and procedures developed within the institution with the approval of the pharmacist in charge for a period of not less than two (2) years. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-12; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1641)*

856 IAC 1-28.1-13 Drug self-administration

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 13. Self-administration of drugs by patients of an institutional facility shall be permitted only if such use is specifically authorized by the treating or ordering physician and:

(1) the patient's knowledge of self-administration has been evaluated; or

(2) the patient has received training in the proper manner of self-administration:

(A) by a pharmacist; or

(B) according to hospital policy; and

there is no risk of harm to the patient. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-13; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1642)*

856 IAC 1-28.1-14 Patient's own medication

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 14. (a) An institutional pharmacy is prohibited from accepting and dispensing drugs that are brought into the institution by the patient, even if intended for use by that same patient. However, use of the patient's own medication may be permitted if:

(1) the patient or the patient's representative may maintain the patient's own medication:

(A) at the bedside; or

(B) for drugs with special storage requirements, including, but not limited to, refrigeration in an appropriate storage area in the patient care area under control of nursing personnel for appropriate administration to that patient only; and

(2) the nurses in charge of that patient's care shall witness the administration and maintain records of such use.

(b) If the patient or the patient's representative brings in medication part or all of which is still present at such time a patient expires, those drugs shall be delivered to the institutional pharmacy for appropriate destruction. Such drugs may not be turned over to the patient's representatives. This rule shall be made clear to the parties involved prior to the permission to use such medication. Patients who are discharged shall take with them their own medications brought to the institution under the terms of this section.

(c) In the event the patient is discharged and leaves drugs brought in under this section, either deliberately or inadvertently, such drugs shall be documented and stored at the appropriate nursing location for a maximum of seven (7) calendar days. If not claimed by the patient or the patient's agent within those seven (7) calendar days, the drugs so stored shall be destroyed as described in subsection (b). *(Indiana Board of Pharmacy; 856 IAC 1-28.1-14; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1642)*

856 IAC 1-28.1-15 Inspections

Authority: IC 25-26-13-4
Affected: IC 16-42-3-3; IC 25-26-13-17

Sec. 15. The qualifying pharmacist or pharmacist in charge shall be responsible for the timely inspection of all areas where drugs are stored, used, or administered. The inspection can be carried out by qualified designee and appropriate records kept. The inspection shall verify, at a minimum, the following:

(1) Disinfectants and drugs solely for nontherapeutic external use are stored separately and apart from drugs for internal use or injection.

(2) Drugs requiring special storage conditions are appropriately stored to assure the drugs are not adulterated as described in IC 16-42-3-3.

(3) Drugs subject to deterioration are removed from any accessible location prior to the expiration date (manufacturer's or other such as required under 856 IAC 1-21) and disposed of appropriately.

(4) Emergency drugs designated by the institution are in adequate supply and are properly stored in the institution.

(5) All necessary and required security and storage standards are met.

(6) All pharmacy-related policies and procedures of the institution are complied with.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-15; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1642)

Rule 29. Electronic Data Processing of Prescriptions

856 IAC 1-29-1 Approval of electronic data processing system

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 1. (a) No electronic data processing system may be used by a pharmacist pursuant to a Type I, Type III, and Type VI pharmacy permit as an alternative to his or her recordation of prescription information unless that system has been approved by the Indiana board of pharmacy (board).

(b) No electronic data processing system may be used by a pharmacist as an alternative to his recordation of information directly on the original prescription pursuant to IC 25-26-13-25(c), without the approval of the board, and such an electronic data processing system does not qualify for approval unless it satisfies at a minimum the requirements found in this rule. Any such system must be approved by the board before initial installation in Indiana. Any pharmacy installing such a system must make a written request to the board for approval. Approval is subject to withdrawal for cause so that the pharmacist must in such a case discontinue use of the system as an alternative. *(Indiana Board of Pharmacy; 856 IAC 1-29-1; filed Aug 16, 1984, 3:55 p.m.: 7 IR 2543; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1337)*

856 IAC 1-29-2 On-line retrieval and printout capabilities; data requirements; discontinuance of system

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 2. (a) Any such proposed computerized system must provide on-line retrieval (via visual display device or hard-copy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. This shall include:

(1) prescription number;

(2) date of issuance of the original prescription order by the prescriber;

(3) full name and address of the patient;

(4) name and address of prescriber;

(5) DEA number of prescriber when drug prescribed is controlled substance;

(6) the name, strength (if applicable), dosage form, and quantity of medication originally dispensed;

(7) total number of refills authorized by prescriber.

(b) In addition to the information contained in subsection (a) above, the following information shall be maintained for each filling:

(1) date dispensed;

(2) quantity dispensed, if different from the quantity prescribed;

(3) identification of dispensing pharmacist;

(4) adequate information to determine the number of authorized refills remaining.

(c) The system shall be able to produce a complete printout of current prescription status that would provide all necessary refill information for use in the event that the pharmacy wishes to discontinue use of the computer system. The report shall list all currently refillable prescriptions in sequence by prescription number. The following information shall be included:

(1) prescription number;

(2) date dispensed, quantity, and pharmacist's identification;

(3) the number of refills presently remaining and the amount owed, if any, from any partial refills.

(Indiana Board of Pharmacy; 856 IAC 1-29-2; filed Aug 16, 1984, 3:55 pm: 7 IR 2544; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-29-3 Hard-copy of daily dispensing; verification and retention; back-up capability

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 3. (a) A pharmacy using an electronic data processing system must provide a separate hard-copy printout of prescription order and refill data for each day's dispensing or other board approved uniformly maintained readily retrievable system. This hard-copy printout or other board approved system shall include the following:

(1) prescription number;
(2) date of dispensing;
(3) patient name;
(4) drug and strength (if applicable);
(5) quantity dispensed;
(6) prescriber identification;
(7) pharmacist identification;
(8) refill status;
(9) controlled drug schedule identification.

(b) The dispensing pharmacist must verify that the data is correct to the best of his knowledge and date and sign the document or log book in the same manner as he would sign a check or legal document.

(c) This documentation shall be maintained for a period of five (5) years from the dispensing date. The daily hard-copy printout may be replaced with a monthly printout or other permanent documentation containing the same information.

(d) Each system must have the capability of informational back-up and such documentation must be stored in a secure location. *(Indiana Board of Pharmacy; 856 IAC 1-29-3; filed Aug 16, 1984, 3:55 pm: 7 IR 2544; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-29-4 Auxiliary system

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 4. In the event that a pharmacy which employs such an electronic data processing system experiences system down time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line service. However, nothing in this section shall preclude a pharmacist from using his professional judgment to benefit the health of the patient. *(Indiana Board of Pharmacy; 856 IAC 1-29-4; filed Aug 16, 1984, 3:55 pm: 7 IR 2544; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-29-5 Safeguards

Authority: IC 25-26-13-4
Affected: IC 25-26-13-15; IC 25-26-13-25

Sec. 5. When utilizing electronic data processing systems, pharmacists shall comply with IC 25-26-13-15. *(Indiana Board of Pharmacy; 856 IAC 1-29-5; filed Aug 16, 1984, 3:55 pm: 7 IR 2545; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-29-6 Data entry; supervision

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 6. When electronic data processing equipment is utilized in any pharmacy, input of drug information shall be performed by a pharmacist or under the immediate and personal supervision of a pharmacist. The pharmacist must certify the accuracy of the information entered and verify the prescription order. *(Indiana Board of Pharmacy; 856 IAC 1-29-6; filed Aug 16, 1984, 3:55 pm: 7 IR 2545; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-29-7 Existing systems; compliance date (Repealed)

Sec. 7. *(Repealed by Indiana Board of Pharmacy; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)*

856 IAC 1-29-8 Transfer of prescriptions between pharmacies (Repealed)

Sec. 8. *(Repealed by Indiana Board of Pharmacy; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2249)*

856 IAC 1-29-9 Applicability of rule
Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 9. This rule applies to pharmacies with Type I, Type III, Type IV, and Type VI permits. *(Indiana Board of Pharmacy; 856 IAC 1-29-9; filed Aug 16, 1984, 3:55 p.m.: 7 IR 2545; filed Mar 8, 1989, 10:00 a.m.: 12 IR 1634; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; filed Sep 21, 1992, 9:00 a.m.: 16 IR 724; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

Rule 30. Sterile Pharmaceuticals; Preparation and Dispensing

856 IAC 1-30-1 Purpose
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 1. The purpose of this rule is to provide standards for the preparation, labeling, and distribution of sterile pharmaceutical products by licensed pharmacists, pursuant to a drug order or prescription. *(Indiana Board of Pharmacy; 856 IAC 1-30-1; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-2 "Biological safety cabinet" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 2. As used in this rule, "biological safety cabinet" means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment. *(Indiana Board of Pharmacy; 856 IAC 1-30-2; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-3 "Class 100 environment" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 3. As used in this rule, "Class 100 environment" means an atmospheric environment which contains less than one hundred (100) particles five-tenths (0.5) microns in diameter per cubic foot of air. *(Indiana Board of Pharmacy; 856 IAC 1-30-3; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-4 "Cytotoxic" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 4. As used in this rule, "cytotoxic" means a pharmaceutical that has the capability of killing living human cells. *(Indiana Board of Pharmacy; 856 IAC 1-30-4; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-5 "Qualified pharmacist" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 5. As used in this rule, "qualifying pharmacist" means a licensed pharmacist, identified in the policy and procedure manual, required by section 7 of this rule, as responsible for the preparation of the sterile pharmaceuticals, in compliance with the policy and procedure manual and the applicable laws governing the practice of pharmacy in Indiana. *(Indiana Board of Pharmacy; 856 IAC 1-30-5; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1337)*

856 IAC 1-30-6 "Sterile pharmaceutical" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 6. As used in this rule, "sterile pharmaceutical" means a dosage form of a drug, free from living micro-organisms. *(Indiana Board of Pharmacy; 856 IAC 1-30-6; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-7 Policy and procedure manual

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 7. Each pharmacy preparing and dispensing sterile pharmaceuticals shall maintain a policy and procedure manual relating to sterile products as part of the pharmacy policy and procedure manual or as a separate policy and procedure manual. This manual shall be available at the pharmacy for inspection by the board or its designated inspector. The manual shall be reviewed annually by the pharmacist-in-charge and revised if needed. The manual shall include the name of the pharmacist-in-charge of the preparation of sterile pharmaceuticals and policies and procedures for the following:

(1) Clinical services provided.
(2) The handling, storage, disposal, and clean-up of accidental spills of cytotoxic drugs, if they are prepared.
(3) Disposal of unused supplies and drugs.
(4) Drug destruction and returns.
(5) Drug dispensing.
(6) Drug labeling and relabeling.
(7) Drug storage.
(8) Duties and qualifications for professional and nonprofessional staff.
(9) Equipment.
(10) Handling of infectious wastes, if drug products or administration devices are returned to the pharmacy after administration in the case of home administration.
(11) Infusion devices and drug delivery systems, if utilized.

(12) Investigational drugs, if dispensed.
(13) Quality assurance procedures to include the following:
(A) Recall procedures.
(B) Storage and expiration dating.
(C) Educational procedures for professional staff, nonprofessional staff, and patient, if needed, in the case of home administration.
(D) Sterile procedures to include monitoring the temperature of the refrigerator, routine maintenance, and report of hood certification.
(E) Sterility testing or monitoring, if employed, in the case of routine bulk compounding from nonsterile chemicals.
(14) Reference manuals.
(15) Sterile product preparation procedures.

(Indiana Board of Pharmacy; 856 IAC 1-30-7; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1018, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-8 Physical requirements

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 8. (a) A licensed pharmacy preparing sterile pharmaceuticals shall have a designated area for preparing compounded, sterile pharmaceuticals. The designated area shall be restricted to only those personnel authorized for the preparation of sterile pharmaceuticals. This area may be in a separate room or in a portion of a larger room. The area cannot be a warehouse or stockroom setting, and must be free of dust and dirt.

(b) The designated preparation area shall be used only for the preparation of sterile pharmaceutical products and related functions.

(c) The licensed pharmacy preparing sterile pharmaceutical products shall have the following equipment:
(1) An environmental control device capable of maintaining at least a Class 100 environment in the work space where critical objects are exposed and critical activities are performed. Examples of appropriate devices include laminar airflow hood and zonal laminar flow of high efficiency particulate air (HEPA) filtered air.
(2) A sink with hot and cold running water which is convenient to the compounding area for the purpose of hand scrubs prior to compounding.
(3) Disposal containers for used needles, syringes, gowns, gloves, etc., and, if applicable, cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patients.
(4) Environmental controls including biohazard cabinetry when cytotoxic drug products are prepared.
(5) A refrigerator with a thermometer.

(d) The licensed pharmacy preparing sterile pharmaceuticals shall include the following supplies:
(1) Disposable needles, syringes, and other supplies needed for aseptic admixture.
(2) Disinfectant cleaning solutions.
(3) Hand washing agent with antibacterial action.
(4) Disposable towels or wipes.
(5) Filters and filtration equipment, if utilized.
(6) A cytotoxic drug spill kit shall be available in the facility, if cytotoxic drugs are prepared.
(7) Disposable gowns and gloves.

(e) No one may have access to the pharmacy in the absence of the pharmacist, except as stated in 856 IAC 1-28-7.

(f) A pharmacy preparing sterile pharmaceuticals shall have in its reference library:
(1) the Handbook on Injectable Drugs, published by the American Society of Hospital Pharmacists (ASHP), 4630 Montgomery Avenue, Bethesda, Maryland 20814;
(2) the King's Guide to Parenteral Admixtures, published by Pacemarq Inc., 11701 Borman Drive, St. Louis, Missouri 63146; or
(3) other electronic data base for determining mixing and administration guidelines and drug incompatibilities;

in addition to other publications as required in 856 IAC 1-6-2.

(g) If the pharmacy is handling or preparing cytotoxic drugs, the pharmacy shall have a copy of Occupational Safety and Health Administration requirements for handling cytotoxic drugs as published in Occupational Safety and Health Administration Publication 8-1.1, Office of Occupational Medicine, Directorate of Technical Support, Occupational Safety and Health Administration, U.S. Department of Labor. *(Indiana Board of Pharmacy; 856 IAC 1-30-8; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1018, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; errata filed Mar 17, 1992, 10:20 a.m.: 15 IR 1394; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-9 Personnel

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 9. (a) Each pharmacist engaged in preparing sterile pharmaceuticals must be trained in the specialized functions of preparing and dispensing compounded, sterile pharmaceuticals, including the principles of aseptic technique and quality assurance. Documentation of such training or experience shall be made available for inspection by the board or its representatives.

(b) The qualifying pharmacist shall be responsible for the purchasing, storage, compounding, repackaging, dispensing, and distribution of all sterile pharmaceuticals.

(c) The qualifying pharmacist shall also be responsible for the development and continuing review of all policies and procedures, training manuals, and quality assurance programs. *(Indiana Board of Pharmacy; 856 IAC 1-30-9; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1019, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1337)*

856 IAC 1-30-10 Support personnel

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 10. (a) The pharmacist may be assisted by support personnel in compliance with IC 25-26-13-18(a)(4). Such personnel shall have specialized training in the preparation of sterile pharmaceuticals and shall work under the supervision of a licensed pharmacist. The training provided to these personnel shall be described in writing. The duties and responsibilities of supportive personnel must be consistent with their training and experience.

(b) This section is not to preclude other licensed health care professionals, as allowed by law, may also prepare sterile pharmaceuticals when there is an immediate need, or when the preparation in a pharmacy is not practical. *(Indiana Board of Pharmacy; 856 IAC 1-30-10; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1019, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-11 Staffing

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 11. A pharmacist shall be accessible at all times to respond to patients' and other health professionals' questions and needs. *(Indiana Board of Pharmacy; 856 IAC 1-30-11; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1019, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-12 Profile or medication record system

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 12. A pharmacy-generated profile or medication record system for sterile pharmaceuticals administered to patients, except for those inpatients in an institutional facility, as defined in 856 IAC 1-28-1(a), holding a Type II pharmacy permit, shall be maintained separately from the prescription file. The patient profile or medication record system shall contain at a minimum the following:

(1) Patient's name, date of birth or age, weight, and sex.

(2) Sterile pharmaceutical products dispensed.

(3) Drug content and quantity.

(4) Directions for the patient, if administered outside the facility.

(5) Identification of the dispensing pharmacist and other authorized personnel responsible for preparing the sterile pharmaceutical.

(6) Other drug therapy information, if applicable.

(7) Known or suspected drug sensitivities and allergies of the patient to drugs and foods, if applicable.

(8) Primary diagnosis and chronic conditions if the sterile pharmaceutical is administered outside the facility.

(Indiana Board of Pharmacy; 856 IAC 1-30-12; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1019, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-13 Labeling

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 13. (a) Each sterile pharmaceutical product dispensed to a patient shall be labeled with the following:

(1) Date of preparation by the pharmacy.

(2) Patient name and bed number, if an institutionalized patient.

(3) Name of each drug in the preparation, strength, and amount.

(4) Expiration date of the preparation, including time, if applicable.

(5) Identity of the pharmacist compounding and dispensing the sterile pharmaceutical, and identity of other authorized personnel preparing the product, if applicable.

(6) Other information required by the dispensing pharmacy regarding storage requirements or special warnings.

(b) In addition, if the patient residing at home or outside the facility where the sterile pharmaceutical is prepared, the following labeling requirements apply:

(1) Identifying prescription number.

(2) Prescriber’s full name.

(3) Name, address, and telephone number of the licensed pharmacy.

(4) Directions for use shall be provided, either on the label or by other written instructions, including infusion rate and date and time of administration.

(Indiana Board of Pharmacy; 856 IAC 1-30-13; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1020, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; errata filed Mar 17, 1992, 10:20 a.m.: 15 IR 1394; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1337)

856 IAC 1-30-14 Records and reports

Authority: IC 25-26-13-4
Affected: IC 25-26-13-15; IC 25-26-13-18

Sec. 14. (a) The qualifying pharmacist shall be responsible for such records and reports as required to ensure the patient’s health, safety, and welfare. Such records shall be readily available and maintained for two (2) years from the date of issuance of the prescription or drug order and be subject to inspection by the Indiana board of pharmacy or its designated inspector. These records shall include the following:

(1) Patient profile or medication record system.

(2) Policy and procedure manual.

(3) Training manuals.

(4) Policies and procedures for disposal of cytotoxic waste, when applicable.

(b) Information regarding individual patients shall be maintained in a manner to assure confidentiality of the patient's record. Release of this information shall be in accordance with IC 25-26-13-15. *(Indiana Board of Pharmacy; 856 IAC 1-30-14; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1020, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1338)*

856 IAC 1-30-15 Disposal of infectious waste

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 15. The qualifying pharmacist is responsible for assuring that there is a system for the disposal of infectious waste returned from outside the facility in a manner consistent with the protection of the public's health and safety and in compliance with applicable state and federal law. *(Indiana Board of Pharmacy; 856 IAC 1-30-15; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1020, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1338)*

856 IAC 1-30-16 Emergency kit

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 16. When sterile pharmaceuticals are provided to home care patients, the dispensing pharmacy may supply the nurse with emergency drugs, if the treating physician has authorized the use of such drugs by a protocol, for use in an emergency situation, e.g., anaphylactic shock. *(Indiana Board of Pharmacy; 856 IAC 1-30-16; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1020, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-17 Cytotoxic drugs

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 17. The following additional requirements are necessary to ensure the protection of the personnel involved in those licensed pharmacies that prepare cytotoxic drugs:

(1) All cytotoxic drugs shall be compounded in a vertical flow, Class II, biological safety cabinet.

(2) Protective apparel shall be worn by personnel compounding cytotoxic drugs. This shall include disposable gloves and gowns with tight cuffs.

(3) Appropriate safety and special handling techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.

(4) Procedures for disposal of cytotoxic waste shall be specified within the policy and procedure manual as required by section 7 of this rule.

(5) Written procedures for handling both major and minor spills of cytotoxic agents must be developed and included in the policy and procedure manual.

(6) Cytotoxic agents shall be properly labeled to identify the need for caution in handling, e.g., "Chemotherapy-Dispose of Properly". If shipped, the outer container must also be properly labeled with the same cautionary statement.

(Indiana Board of Pharmacy; 856 IAC 1-30-17; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1020, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-18 Quality assurance

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 18. (a) The designated qualifying pharmacist shall conduct a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. Samples of finished products shall be examined, or other continuous monitoring methods shall be used to assure that the pharmacy is capable of consistently preparing sterile pharmaceuticals meeting their specifications. Quality assurance procedures shall include the following:

(1) Recall procedures for compounded sterile pharmaceuticals.

(2) Storage and dating for compounded sterile pharmaceuticals.

(3) Sterile procedures, including the following:

(A) Monitoring the temperature of the refrigerator.

(B) Routine maintenance.

(C) Report of laminar flow hood certification.

(4) Written documentation of periodic hood cleaning.

(b) All biological safety cabinets and Class 100 environments shall be certified by an independent contractor or facility specialist as meeting Federal Standard 209B or National Sanitation Foundation Standard 49, as referenced in section 2 of this rule, for operational efficiency. Such certification shall be performed at least annually. Records documenting certification shall be maintained for a period of not less than two (2) years.

(c) Prefilters for the clean air source shall be replaced or cleaned as applicable on a regular basis and the replacement or cleaning date documented.

(d) A vertical flow Class II biological safety cabinet may be used to compound any sterile pharmaceutical product; however, it must be thoroughly cleaned between each use for cytotoxic and noncytotoxic drug compounding.

(e) If manufacturing of parenteral solutions is performed utilizing nonsterile chemicals, extensive end product testing, as referenced in Remington's Pharmaceutical Sciences, published by Mack Publishing Company, Easton, Pennsylvania 18042, or other Federal Drug Administration approved testing methods, must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter, microbial contamination, and testing for pyrogens. This does not preclude the extemporaneous compounding of certain sterile pharmaceuticals.

(f) There shall be written justification of the chosen expiration dates for compounded parenteral products documented in the policy and procedure manual.

(g) There shall be documentation of quality assurance audits at planned intervals, including infection control and sterile technique audits. *(Indiana Board of Pharmacy; 856 IAC 1-30-18; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1021, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1338)*

Rule 31. Facsimile Machines

856 IAC 1-31-1 "Facsimile machine" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13-2

Sec. 1. As used in this rule, "facsimile machine" means a machine that electronically transmits exact images through connection with a telephone network. *(Indiana Board of Pharmacy; 856 IAC 1-31-1; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1390; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-31-2 Use of a facsimile machine to electronically transmit a prescription or drug order

Authority: IC 25-26-13-4
Affected: IC 25-1-9; IC 25-26-13

Sec. 2. Prescription or drug orders for legend drugs may be transmitted by facsimile machine from an authorized prescribing

practitioner to a pharmacy under the following restrictions:

(1) The original prescription or order transmitted by facsimile machine contains:

(A) all information required under IC 25-26-13-2;

(B) the name and address of the pharmacy to which the prescription or drug order is being transmitted; and

(C) the name of the person transmitting the prescription or drug order.

(2) A statement that the prescription is valid only if transmitted by facsimile machine is included on the face of the original prescription or drug order.

(3) Actual transmission is done by or under the direct supervision of the authorized prescribing practitioner or by an authorized agent.

(4) A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's authorized agent to a pharmacy via facsimile equipment, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in subdivision (5) or (6).

(5) A prescription prepared in accordance with 856 IAC 2-6-4 written for a Schedule II narcotic substance to be compounded for the direct administration to a patient in a private residence, long term care facility, or hospice setting by means of parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent by facsimile. The facsimile serves as the original written prescription, and it shall be maintained in accordance with IC 25-26-13-25.

(6) A prescription prepared in accordance with 856 IAC 2-6-4 written for a Schedule II substance for a resident of a long term care facility licensed under 410 IAC 16.2-3.1 may be transmitted by the practitioner or the practitioner's authorized agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for the purpose of this subdivision, and it shall be maintained in accordance with IC 25-26-13-25.

(7) A prescription prepared in accordance with 856 IAC 2-6-4 written for a Schedule II narcotic substance for a patient enrolled in a hospice program, inpatient or outpatient, certified by Medicare under Title XVIII or licensed by Indiana may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this subdivision and maintained in accordance with IC 25-26-13-25.

(8) A controlled substance prescription or drug order for a Schedule III, IV, or V controlled substance may be sent by facsimile machine and must be sent by the prescribing practitioner or an authorized agent.

(9) A facsimile machine transmitted copy of a prescription or drug order must produce a nonfading copy or be reduced to writing, either manually or via other processes, for example, photocopying, that produces a nonfading document. Proper notation on the file copy shall indicate that the prescription order was initially received via facsimile machine transmission.

(10) The receiving facsimile machine must be located in the prescription department of the pharmacy or in another nonpublic area of the pharmacy to protect patient/pharmacist/authorizing prescribing practitioner confidentiality and security as required by IC 25-26-13-15.

(11) Using facsimile equipment to circumvent documentation, authenticity, verification, or other standards of the profession of pharmacy will be considered professional incompetence under IC 25-1-9.

(Indiana Board of Pharmacy; 856 IAC 1-31-2; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1390; filed Aug 17, 1995, 8:30 a.m.: 19 IR 39; filed May 26, 2000, 8:52 a.m.: 23 IR 2502; filed May 10, 2001, 9:22 a.m.: 24 IR 3067; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

Rule 32. Transfer of Prescriptions Between Pharmacies

856 IAC 1-32-1 Applicability of rule

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 1. This rule governs the transfer of prescription information, either originally filled or previously refilled, by one (1) pharmacy to another pharmacy for refills. *(Indiana Board of Pharmacy; 856 IAC 1-32-1; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1339)*

856 IAC 1-32-2 Noncontrolled and controlled substance prescription transfers

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 2. (a) Prescription information for legend drugs that are not controlled substances may be transferred at any time during the lifetime of the prescription up to one (1) year after the date of the original filling, or when the original number of authorized refills expires, whichever comes first.

(b) Except as limited by the requirement of subsection (a), prescriptions for legend drugs that are not controlled substances may be transferred any number of times.

(c) If any authorized refills remain, prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances may be transferred only once within six (6) months from the date the prescription was issued. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(d) Prescriptions for Schedule II controlled substances may not be transferred. *(Indiana Board of Pharmacy; 856 IAC 1-32-2; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; filed May 26, 2000, 8:52 a.m.: 23 IR 2503; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1339)*

856 IAC 1-32-3 Patient's right to transfer prescriptions

Authority: IC 25-26-13-4
Affected: IC 25-26-13-16; IC 25-26-13-25

Sec. 3. A pharmacist may not legally refuse to transfer a patient's prescription or prescription information except when to do so would be against the professional judgment of the pharmacist in the manner provided for under IC 25-26-13-16. *(Indiana Board of Pharmacy; 856 IAC 1-32-3; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; errata filed Jul 10, 1992, 9:00 a.m.: 15 IR 2465; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1339)*

856 IAC 1-32-4 Pharmacists' responsibilities

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 4. Transfer of prescription information under this rule must meet the following requirements:

(1) The transfer is communicated directly between two (2) licensed pharmacists or by suitable electronic device approved by the Indiana board of pharmacy, and the transferring pharmacist records the following information:

(A) Write the word "VOID" on the face of the invalidated prescription.

(B) Record on the reverse of the invalidated prescription, the name, address, and Drug Enforcement Administration registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription.

(C) Record the date of the transfer and the name of the pharmacist transferring the information.

(2) The pharmacist receiving the transferred prescription shall reduce to writing the following:

(A) Write the word "TRANSFER" on the face of the transferred prescription.

(B) Provide all information required to be on a prescription and include the following:

(i) Date of issuance of original prescription.

(ii) Original number of refills authorized on original prescriptions.

(iii) Date of original dispensing.

(iv) Number of valid refills remaining and date of last refill, and, in the event the transfer is for the second or subsequent transfer of a substance that is a Schedule III, Schedule IV, or Schedule V controlled substance, the date and location of the previous refill.

(v) Pharmacy's name, address, Drug Enforcement Administration registration number, and original prescription number from which the prescription information was transferred.

(vi) Name of the transferor pharmacist.

(C) Both the original and transferred prescription must be maintained as required under IC 25-26-13-25.

(3) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferral.

(Indiana Board of Pharmacy; 856 IAC 1-32-4; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; errata filed Jul 10, 1992, 9:00 a.m.: 15 IR 2465; filed May 26, 2000, 8:52 a.m.: 23 IR 2503; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1339)

Rule 33. Counseling

856 IAC 1-33-1 "Counseling" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13-4

Sec. 1. As used in this rule, "counseling" means effective communication, by a pharmacist, of information in order to improve therapeutic outcomes by maximizing the proper use of prescription medications and devices. *(Indiana Board of Pharmacy; 856 IAC 1-33-1; filed Dec 1, 1992, 5:00 p.m.: 16 IR 1176; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-33-2 Patient counseling requirements

Authority: IC 25-26-13-4
Affected: IC 25-26-13-16

Sec. 2. (a) Upon the receipt of a prescription or upon the subsequent refilling of a prescription, and following a review of the patient's prescription medication profile, the pharmacist shall be responsible for the initiation of an offer to discuss matters (counsel) which, in the pharmacist's professional judgment, are significant to optimizing drug therapy. Depending upon the situation, these matters may include, but are not necessarily limited to, the following:

(1) The name and description of the medicine.

(2) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(3) Special directions and precautions.

(4) Common adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur.

(5) Techniques for self-monitoring drug therapy.

(6) Proper storage.

(7) Prescription refill information.

(8) Action to be taken in the event of a missed dose.

(b) Counseling shall be in person, whenever practicable, or through access to a telephone service which is toll free for long distance calls, and be held with the patient, the patient's caregiver, or the patient's representative.

(c) Alternative forms of patient information may be used to supplement verbal counseling when appropriate. Examples include, written information leaflets, pictogram labels, and video programs. Nothing in this subsection shall be construed to mean that supplements may be a substitute for verbal counseling when verbal counseling is practicable.

(d) Nothing in this rule shall be construed as requiring a pharmacist to provide counseling when a patient refuses the offer to counsel. *(Indiana Board of Pharmacy; 856 IAC 1-33-2; filed Dec 1, 1992, 5:00 p.m.: 16 IR 1176; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-33-3 Patient profile requirements

Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 3. The pharmacist shall assure that prescription medication profiles are maintained for all patients receiving pharmaceutical care at that pharmacy. Within limits of reasonably available information, the pharmacy medication profile shall include the following:

(1) Name, address, telephone number, age or date of birth, and gender.

(2) Known drug allergies and adverse reactions.

(3) A list of current medications and relevant devices, either of which may relate to the patient's drug therapy.
(4) Known disease states.
(5) Any other information that, in the pharmacist's professional judgment, the pharmacist deems appropriate.
(6) Pharmacist's comments relevant to the individual's drug therapy.

(Indiana Board of Pharmacy; 856 IAC 1-33-3; filed Dec 1, 1992, 5:00 p.m.: 16 IR 1176; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-33-4 Institutional patient exception

Authority: IC 25-26-13-4
Affected: IC 25-26-13-4

Sec. 4. The requirements for patient counseling, as described in this rule, shall not apply to patients residing in institutional facilities in Indiana as defined under 856 IAC 1-28-1(a). *(Indiana Board of Pharmacy; 856 IAC 1-33-4; filed Dec 1, 1992, 5:00 p.m.: 16 IR 1177; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

Rule 34. Security Features for Prescriptions

856 IAC 1-34-1 Applicability

Authority: IC 35-48-7-8
Affected: IC 16-42-19-5

Sec. 1. This rule establishes minimum standards for security features for prescriptions issued by practitioners as described in IC 16-42-19-5. Practitioners licensed in Indiana must comply with this rule in order for their prescriptions to be accepted for filling in licensed Indiana pharmacies. *(Indiana Board of Pharmacy; 856 IAC 1-34-1; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2782, eff Jan 1, 1996; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-34-2 Security feature requirements

Authority: IC 35-48-7-8
Affected: IC 16-42-19-5

Sec. 2. (a) All controlled substance prescriptions written by licensed Indiana practitioners, as defined by IC 16-42-19-5, must contain the following security features:

(1) A latent, repetitive "void" pattern screened at five percent (5%) in reflex blue must appear across the entire face of the document when the prescription is photocopied.
(2) There shall be a custom artificial watermark printed on the back side of the base paper so that it may only be seen at a forty-five (45) degree angle. The watermark shall consist of the words "Indiana Security Prescription", appearing horizontally in a step-and-repeated format in five (5) lines on the back of the document using 12-point Helvetica bold type style.
(3) An opaque RX symbol must appear in the upper right-hand corner, one-eighth (⅛) of an inch from the top of the pad and five-sixteenths ($^5/_{16}$) of an inch from the right side of the pad. The symbol must be three-fourths (¾) inch in size and must disappear if the prescription copy is lightened.
(4) Six (6) quantity check-off boxes must be printed on the form and the following quantities must appear and the appropriate box be checked off for the prescription to be valid:
    (A) 1–24
    (B) 25–49
    (C) 50–74
    (D) 75–100
    (E) 101–150
    (F) 151 and over.
(5) No advertisements may appear on the front or back of the prescription blank.
(6) Logos, defined as a symbol utilized by an individual, professional practice, professional association, or hospital, may

appear on the prescription blank. The upper left one (1) inch square of the prescription blank is reserved for the purpose of logos. Only logos, as defined by this subdivision, may appear on the prescription blank.

(7) Only one (1) prescription may be written per prescription blank. The following statement must be printed on the bottom of the pad: "Prescription is void if more than one (1) prescription is written per blank.".

(8) Refill options that can be circled by the prescriber must appear below any logos and above the signature lines on the left side of the prescription blank in the following order:

Refill NR 1 2 3 4 5 Void after_____.

(9) Practitioner name and state issued professional license number must be preprinted, stamped, or manually printed on the prescription.

(10) All prescription blanks printed under this rule shall be four and one-fourth (4¼) inches high and five and one-half (5½) inches wide.

(b) Nothing in this rule shall prevent licensed Indiana practitioners from utilizing security paper prescriptions for the prescribing of any legend drug. *(Indiana Board of Pharmacy; 856 IAC 1-34-2; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2782, eff Jan 1, 1996; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)*

856 IAC 1-34-3 Preprinted controlled substance prohibition

Authority: IC 35-48-7-8
Affected: IC 35-48-2; IC 35-48-7

Sec. 3. The name of any controlled substance, as defined by IC 35-48-2, may not be preprinted on any prescription forms at any time before the prescription is being prepared and executed for presentation to the patient or the patient's agent. That includes, but is not limited to, such activities as typing prescriptions in anticipation of their need, and using a rubber stamp or other similar means which would accomplish the same end. Commercially printed forms containing names of controlled substances are also prohibited. *(Indiana Board of Pharmacy; 856 IAC 1-34-3; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2783, eff Jan 1, 1996; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-34-4 Exemption

Authority: IC 35-48-7-8
Affected: IC 35-48-7

Sec. 4. Prescriptions utilized by pharmacists to record call-in prescriptions, transferred prescriptions, or facsimile prescriptions do not need to comply with this rule. *(Indiana Board of Pharmacy; 856 IAC 1-34-4; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2783, eff Jan 1, 1996; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-34-5 Approval

Authority: IC 35-48-7-8
Affected: IC 35-48-7

Sec. 5. Printers wishing to supply prescription blanks to authorized recipients must obtain a template design from the board to use as a layout guide. Printers must also submit a preprint proof to the board for approval prior to any production of prescription blanks governed by this rule. *(Indiana Board of Pharmacy; 856 IAC 1-34-5; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2783, eff Jan 1, 1996; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

Rule 35. Pharmacy Technicians

856 IAC 1-35-1 Purpose and scope

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. (a) The board is responsible for establishing standards for the competent practice of pharmacy.

(b) The use of pharmacy technicians to assist the pharmacist with nondiscretionary functions associated with the practice of pharmacy enables the pharmacist to provide pharmaceutical care to the patient.

(c) Evolved pharmacy practice demands additional time for pharmacists to counsel individual patients regarding the proper use of drugs.

(d) Only pharmacists (licensed under IC 25-26-13-11), pharmacy interns and externs (as defined in IC 25-26-13-2 and registered under IC 25-26-13-10), and pharmacy technicians as described in this section shall be permitted to participate in the activities associated with a drug order or prescription preparation.

(e) A pharmacist shall not permit a pharmacy technician to participate in the activities associated with a drug order or prescription preparation unless the pharmacy technician meets the qualifications of this section.

(f) The pharmacist is responsible for the work performed by the pharmacy technician under the pharmacist's supervision. *(Indiana Board of Pharmacy; 856 IAC 1-35-1; filed Aug 17, 1995, 8:30 a.m.: 19 IR 39; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; filed Dec 20, 2002, 12:17 p.m.: 26 IR 1561)*

856 IAC 1-35-2 "Unlicensed person" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 2. (a) As used in this rule, "unlicensed person" means a pharmacy technician who, under the immediate and direct supervision of the pharmacist, assists the pharmacist in the technical and nonjudgmental functions related to the practice of pharmacy in the processing of prescriptions and drug orders.

(b) As used in subsection (a), "pharmacy technician" shall not include pharmacy intern/externs or other ancillary persons which include, but are not limited to:

(1) clerks;
(2) secretaries;
(3) cashiers; or
(4) delivery persons;

who may be present in the pharmacy. *(Indiana Board of Pharmacy; 856 IAC 1-35-2; filed Aug 17, 1995, 8:30 a.m.: 19 IR 40; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-35-3 "Pharmaceutical care" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 3. As used in this rule, "pharmaceutical care" means the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. *(Indiana Board of Pharmacy; 856 IAC 1-35-3; filed Aug 17, 1995, 8:30 a.m.: 19 IR 40; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-35-4 Qualifications

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 4. To be eligible to perform the functions and duties of a pharmacy technician, an individual must possess the following qualifications, which shall be ascertained and documented in a reasonably retrievable manner by the pharmacist that qualifies the pharmacy permit:

(1) The individual has not been convicted of a crime that has a direct bearing on the individual's ability to work with legend drugs or controlled substances.

(2) The individual must be a high school graduate or have successfully completed a General Education Development program or have been judged to be competent by the qualifying pharmacist.

(3) The individual must have successfully completed or be enrolled in and successfully complete within twelve (12) months of being hired as a technician one (1) of the following board-approved programs:

(A) A comprehensive curricular-based education and training program conducted by a pharmacy or educational organization.

(B) A technician training program utilized by the employer that includes specific training in the duties required to assist the pharmacist in the technical functions associated with the practice of pharmacy. The contents of the training program shall include, at a minimum, the following:

(i) Understanding of the duties and responsibilities of the technician and the pharmacist, including the standards of patient confidentiality and ethics governing pharmacy practice.

(ii) Tasks and technical skills, policies, and procedures related to the technician's position.

(iii) Working knowledge of pharmaceutical-medical terminology, abbreviations, and symbols commonly used in prescriptions and drug orders.

(iv) Working knowledge of the general storage, packaging, and labeling requirements of drugs, prescriptions, or drug orders.

(v) Ability to perform the arithmetic calculations required for the usual dosage determinations.

(vi) Working knowledge and understanding of the essential functions related to drug purchasing and inventory control.

(vii) The record keeping functions associated with prescriptions or drug orders.

(4) In lieu of the requirements in subdivision (3), the successful completion of a board-approved certification examination may satisfy the requirements of this section.

(5) A record of the pharmacy technician training and education must be maintained in the pharmacy where the technician is employed and shall include the following:

(A) The name of the pharmacy technician.

(B) The starting date of employment as a pharmacy technician.

(C) The starting date of the technician training program.

(D) The date of completion of the training program or proof of passing the board-approved examination if subdivision (4) applies.

(E) A copy of the training manual, if on-the-job training is used by the employer, or certificate of successful completion of another approved program, or other training program completed prior to employment.

(Indiana Board of Pharmacy; 856 IAC 1-35-4; filed Aug 17, 1995, 8:30 a.m.: 19 IR 40; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; filed Dec 20, 2002, 12:17 p.m.: 26 IR 1562)

856 IAC 1-35-5 Duties that a pharmacy technician may not perform

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 5. A pharmacy technician may perform many technical functions associated with the practice of pharmacy. However, even under the immediate and direct supervision of a pharmacist, the pharmacy technician is prohibited from performing the following functions:

(1) Any duty required by law, regulation, or rule to be performed by a pharmacist.

(2) The provision of advice or consultation with the prescriber or other licensed health care provider regarding the patient or the interpretation and application of information contained in the prescription or drug order, medical record, or patient profile.

(3) The provision of advice or consultation with the patient regarding the interpretation of the prescription or the application of information contained in the patient profile or medical record.

(4) Dispensing of prescription drug information to the patient as required in IC 25-26-13-4.

(5) Receipt of a verbal prescription, other than a refill approval or denial, from a prescriber.

(6) Final check on all aspects of the completed prescription and assumption of the responsibility for the filled prescription, including, but not limited to, accuracy of the:

(A) drug;

(B) strength; and

(C) labeling.

(Indiana Board of Pharmacy; 856 IAC 1-35-5; filed Aug 17, 1995, 8:30 a.m.: 19 IR 41; readopted filed Nov 13, 2001, 3:55 p.m.:

25 IR 1330)

856 IAC 1-35-6 Provision of quality assurance; duties (Repealed)

Sec. 6. *(Repealed by Indiana Board of Pharmacy; filed Dec 20, 2002, 12:17 p.m.: 26 IR 1562)*

856 IAC 1-35-7 Identification
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 7. (a) The public shall be able to identify a pharmacist from a pharmacy technician while engaged in the provision of pharmaceutical care.

(b) A pharmacy technician shall:

(1) wear identification clearly stating that the person is a pharmacy technician while on duty; and

(2) identify himself or herself verbally in any telephonic or electronic communication as a pharmacy technician.

(c) No person, other than a person who has met the qualifications established in section 4 of this rule, will be permitted to wear identification using the words "pharmacy technician" or similar wording that may confuse or deceive another person. *(Indiana Board of Pharmacy; 856 IAC 1-35-7; filed Aug 17, 1995, 8:30 a.m.: 19 IR 41; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

Rule 36. Temporary Variances

856 IAC 1-36-1 Exceptions
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. A person subject to the regulations of the board may request that the board grant a temporary variance from any rule adopted by the board, except rules concerning examinations, experience hours, and requirements for licensure. *(Indiana Board of Pharmacy; 856 IAC 1-36-1; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4534; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-36-2 Submission of a request for temporary variance
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 2. A request for a temporary variance must be submitted to the board in writing. Each request must contain the following information:

(1) The name, address, and license or permit number of the applicant.

(2) The name of the responsible pharmacist and the specific location at which activities will be conducted under the temporary variance.

(3) The citation to the specific rule from which the applicant seeks a temporary variance.

(4) A detailed explanation of the purpose of the temporary variance.

(5) An assessment of the impact on the public if the variance is granted.

(6) A statement of the conditions which would cause the applicant to apply for renewal of the temporary variance.

(7) The beginning, midpoint, and ending dates of the proposed demonstration project.

(Indiana Board of Pharmacy; 856 IAC 1-36-2; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4534; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-36-3 Positive impact on delivery of pharmaceutical care
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 3. Temporary variances shall only be granted for demonstration projects which are expected to have a positive impact on the delivery of pharmaceutical care. Justification for that expectation shall be fully explained. The board shall not grant any temporary variance which threatens public health, safety, or welfare. *(Indiana Board of Pharmacy; 856 IAC 1-36-3; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-36-4 Period of time

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 4. The board shall grant a temporary variance for a period of no more than six (6) months. Any person who receives a temporary variance shall submit to the board a written report of the effects of the demonstration project at the midpoint and at the conclusion of the temporary variance. *(Indiana Board of Pharmacy; 856 IAC 1-36-4; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-36-5 Renewal

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 5. A temporary variance may be renewed by the Indiana board of pharmacy (board) for an additional six (6) months. A temporary variance shall not be renewed more than five (5) times. Requests for renewal of a variance shall be submitted in writing to the board not less than thirty (30) days prior to the expiration of the variance and shall contain at least the information required by section 2 of this rule. *(Indiana Board of Pharmacy; 856 IAC 1-36-5; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)*

856 IAC 1-36-6 Revocation

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 6. The board may revoke any temporary variance for cause, including, but not limited to, a finding that the temporary variance poses or may pose a threat to public health, safety, or welfare. The person requesting the temporary variance has the obligation to report any such potential threat to the board immediately upon the discovery of such potential threat, or as soon as possible after such discovery. *(Indiana Board of Pharmacy; 856 IAC 1-36-6; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-36-7 Public notice

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 7. The board shall give public notice of requests for temporary variances at not less than two (2) consecutive regular meetings before voting to grant or deny a request for a temporary variance. *(Indiana Board of Pharmacy; 856 IAC 1-36-7; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-36-8 Justification of denial

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 8. The board shall set forth in writing its reasons for granting or denying a temporary variance. *(Indiana Board of Pharmacy; 856 IAC 1-36-8; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-36-9 Copies of requests

Authority: IC 25-26-13-4
Affected: IC 25-26-13-5

Sec. 9. The executive director shall retain copies of all requests for temporary variances and the board's reasons for granting or denying requests as part of the record of it proceedings maintained under IC 25-26-13-5. *(Indiana Board of Pharmacy; 856 IAC 1-36-9; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

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